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JPL PUBLICATION 80-98

# Total Hip Joint Replacement Biotelemetry System

J.F. Boreham  
R.B. Postal  
R.A. Luntz



(NASA-CR-164529) TOTAL HIP JOINT  
REPLACEMENT BIOTELEMETRY SYSTEM (Jet  
Propulsion Lab.) 76 p HC A05/MF A01

N81-27785

CSSL 06B

Unclas  
63/52 26797

May 1, 1981

National Aeronautics and  
Space Administration

Jet Propulsion Laboratory  
California Institute of Technology  
Pasadena, California

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**National Aeronautics and  
Space Administration**

**Jet Propulsion Laboratory  
California Institute of Technology  
Pasadena, California**

The research described in this publication was carried out by the Jet Propulsion Laboratory, California Institute of Technology, under contract with the National Aeronautics and Space Administration.



### ACKNOWLEDGEMENTS

The authors would like to acknowledge the close collaboration on this project of Professor Keith L. Markolf of UCLA School of Medicine; and at JPL, Mr. John Rice for the mechanical design; Mr. Charles Cruzan for the assembly procedures; and Mr. John Meysenburg for the testing of the telemetry system.

## ABSTRACT

The report describes the development of a biotelemetry system that is hermetically sealed within a total hip replacement implant. This task was performed through a cooperative effort between JPL and the Biomechanics Section of the Division of Orthopedic Surgery at UCLA. The telemetry system transmits six channels of stress data in order to reconstruct the major forces acting on the neck of the prosthesis and uses an induction power coupling technique to eliminate the need for internal batteries. The report discusses the activities associated with the telemetry micro-miniaturization, data recovery console, hardware fabrications, power induction systems, electrical and mechanical testing and hermetic sealing test results.

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## INTRODUCTION AND BACKGROUND

Over 100,000 total hip-replacement operations are performed a year in the U.S.A. X-ray evidence of femoral component looseness has been noted to be in excess of 20 percent in published series from the Mayo Clinic (1) in 1978 and UCLA in 1979 (2). It has been reported that failures occurred due to prosthetic loosening with subsidence in up to 24 percent of patients in as little as seven years, and a failure-rate of 54 percent after only five years in patients under thirty years of age. Femoral component stem breakage has been reported to vary from .23 to 8 percent. These numbers are expected to escalate as total hips are implanted into increasing numbers of younger active patients who have expectations of increased performance over their diseased joints. Mechanical complications of implant breakage, cement fracture, skeletal loosening and component wear are directly related to the transmission of force across the joint.

In 1977 under a Caltech President's Fund Grant, JPL in cooperation with the Biomechanics Section of the Division of Orthopedic Surgery at UCLA began the development of a prototype biotelemetry package to be sealed within a total hip replacement implant. The objectives were to develop and demonstrate feasibility of a microminiature telemetry package suitable for installation within a 38 mm ball of a hip replacement prosthesis. A paper describing this task and entitled "Biotelemetry from a Total Hip Replacement Prosthesis" was published in Biotelemetry IV 1978 and is given in Appendix A. Upon completing the objectives of the President's Fund Grant, this development effort was continued under NASA sponsorship in FY 1978 to: 1) complete a more detailed design of the telemetry electronics, 2) develop the hermetic sealing procedures, 3) design power induction and data recovery systems and 4) demonstrate a fully instrumented and sealed prosthesis with a 35 mm ball diameter.

This report discusses the activities associated with the telemetry microminiaturization, data recovery console, hardware fabrications, power induction system, electrical and mechanical testing and hermetic sealing test results.

Figure 1 shows different types of hardware fabricated during this program. Table 1 details their configurations and the types of tests performed on each unit. As shown, the Engineering Model has undergone all operations except hermetic sealing.

Load tests of the Engineering Model prosthesis indicate the recovered telemetered strain data can reproduce the load vectors with an uncertainty of less than 9%. Power induction system tests with the Engineering Model implanted in a cadaver leg showed adequate power transfer with sufficient margin. RF transmission tests in a simulated implant configuration indicate expected clinical data signal to noise ratio will be 39 dB which corresponds to a noise corruption error of 1.2%.

As of the date of this report the two final models being built under this effort are in process and are 50% complete. These models, the prototype and proof test model, both with the final prosthesis form are fully instrumented with one hermetically sealed.

A UCLA grant application to NIH for follow-on sponsorship of this program has been submitted and is pending NIH approval. The objective of the NIH phase will be to complete human-use and reliability efforts to gain human-use acceptance and satisfy requirements for the clinical environment. The continued effort between UCLA and JPL is leading to eventual implantation of the telemetry system to allow for the in-vivo measurements of loading of the prosthesis for a variety of patient activities.

## SYSTEM DESCRIPTION

The biotelemetry system is described in pages 22 and 23 of the NIH Grant Application (Appendix B), while a block diagram and a pictorial view of the prosthesis showing system elements are in Figures 1 and 2, respectively of the same document. The telemetry and power induction concepts were initially developed at UCLA by research assistants G. K. Tham (3), W. K. Buklen (4) and T. Norwicki (5) under the direction of Dr. K. L. Markoff of the Orthopedic Surgery Division and Professor J. Willis of the School of Engineering. The system design is similar to that suggested by Carlson (6) in that it utilizes a time multiplexed PAM/FM telemetry format and an external power induction source.

The conceptual circuits were further developed at JPL under NASA sponsorship beginning in FY 1978. Major activities included: 1) microminiaturization of the electronics to fit within the prosthesis shell using planetary spacecraft technology, 2) redesign of the power induction system for stability and improved power transfer efficiency, 3) development of strain gauging techniques, 4) development of methods of testing, 5) development of methods of proving reliability and 6) design and assembly of a data recovery system. A description of the system elements, problems encountered and their solutions as well as test results are given below.

## TELEMETRY SYSTEM

The telemetry system consists of 1) a 10 channel time-based multiplexer submodule, 2) a pulse amplitude modulated FM (PAM/FM) transmitter submodule and 3) a stem wound power induction secondary coil and FM antenna. A detailed description of the telemetry electronics is given in Appendix B page 23. The only problems associated with the telemetry design were imbalance in the multiplex sequencer output levels and excessive DC power required in the voltage regulator circuitry. The sequencer output imbalances were corrected by adding a balance resistor between strain gauge pairs in each of the data channel outputs. DC power required for the regulator was reduced 50% by utilizing a more recently designed, more efficient regulator chip. Typical system electrical performance parameters are listed in Table 2.

## POWER INDUCTION SYSTEM

The power induction system is designed to eliminate the need for internal batteries. The system consists of a pair of loosely coupled coils. The

primary is worn around the patient's thigh and is powered by a 250 kHz portable oscillator worn around the waist. The teflon coated gold wire secondary coil is located at the prosthesis tip. A further description of the power induction system is given in Appendix B page 24. Problems encountered with the power induction system development include frequency stability and poor power transfer efficiency. The original design used a single stage power oscillator with no isolation between the oscillator and induction coil. Tests show that frequency stability can be greatly improved through the use of a 3-stage unit consisting of an oscillator, buffer and power amplifier. The power amplifier circuit design has been completed. The power transfer problem was solved by a redesign of the external induction coil and by decoupling the internal secondary coil from the prosthesis stem with a dielectric layer. A further discussion with test results is given in Appendix C pages 4 and 5.

### STRAIN GAUGE SENSORS

Semiconductor strain gauges were selected for this telemetry system because of their high sensitivity to strain, small size and low power consumption. Problems encountered with the gauging include the gauge placement, carrier size and shape and gauge temperature coefficient. Improper placement of the strain gauges resulted in erroneous readings. The strain gauge carrier size and shape was not consistent between parts, which made accurate gauge placement difficult. The manufacturer was consulted and closer tolerances were specified. In addition, the I.D. of the neck was broached flat to the width of the gauge carriers in the eight equally spaced gauge locations to facilitate accurate placement. A description of gauge location is given in Appendix C page 5.

The temperature coefficient problem was minimized by adding a dummy gauge, mechanically isolated from the neck but in close proximity to the active gauges, to the bridge network to compensate for temperature variations.

### MECHANICAL LOADING/STRESS MEASUREMENTS

It is of prime importance to assure that overall telemetry system sensitivities along with measurement resolution and accuracies will be sufficient to meet clinical data recovery requirements. Static stress tests at JPL of a mechanical model prosthesis ball and neck region complete with strain gauges and a telemetry assembly have shown that load components can be reconstructed from telemetered output data with an uncertainty of less than 9 percent.

The problems of the mechanical loading and stress measurements were attributed to the strain gauges and are covered in the strain gauge explanation. However, near the conclusion of the planned series of static stress tests on the development model prosthesis, the force controller exceeded preset limits with the unit in the 90° tilt position. The maximum force applied before control was restored reached 5100 lb (2313 kg) and resulted in a permanent deflection of the ball and neck region of 3.5 degrees from the original axis of symmetry. This "test", therefore, established a measure of the factor of safety in the mechanical design. For more detail see Appendix B pages 23 and 24.

## VIBRATION TESTING

The EM prosthesis has undergone sinusoidal vibration from 5 to 22 Hz at 0.4 inch double amplitude and from 22 Hz to 2 kHz at 10 G peak. The system was monitored during testing and maintained its integrity, both mechanically and electrically. There were no problems encountered during or after this test.

## SEALING TESTS

Since the prosthesis shell represents the primary barrier between the recipient's tissue and body fluids and the internal electronic components, considerable design effort has been expended to insure that it (1) can be completely sealed with minimal effect on the internal electronics, (2) has sufficient strength not to break, and (3) can be tested after assembly. Electron Beam (E-beam) welding was chosen as the best sealing method that satisfies all the above requirements.

One of the main concerns of this welding process is the effect of heat produced by the electron beam on the internal electronic components. Another concern is the seal itself: How well it prevents fluids from entering the prosthesis. To assess the temperature effects on the internal electronics, several sample prostheses were instrumented for internal temperature profiles near the weld joint during sealing operations. It was determined that during sealing, temperatures beyond 0.125 in. (0.32 cm) from the joint did not exceed 121°C (394 K) which is well within the manufacturer's ratings for all components used. The temperature at the sensitive semiconductor strain gauge locations is not expected to exceed 50°C (323 K) during the processing, which is well below the manufacturer's maximum operating temperature of 175°C (448 K). A prosthesis with a telemetry assembly installed was then sealed to assess the effects of sealing on the telemetry functions. A comparison of measurements before and after sealing showed the welding operation had no effect on the telemetry electronics. For more information see Appendix B page 25.

## SIMULATED IMPLANT TESTS

Two separate tests of the Engineering Model prosthesis: 1) implanted in a fresh cadaver leg and 2) suspended in a 4 liter water bath were performed to assess the functional performance of the telemetry electronics in a simulated implant configuration. In the cadaver tests the power induction system performed with adequate margin for an external coil placement range of  $\pm 9$  cm from the nominal location. In the water bath test configuration, FM transmission tests of the received RF signal showed an additional loss of only 4 dB with respect to a comparable test in free air. From this data, expected received data S/N was calculated to be 39 dB for a distance of 2 meters. These tests are further detailed in Appendix C pages 4 and 5. The system currently uses a receiver with a 500 kHz bandwidth. Because the peak deviation can reach 50 kHz at 500  $\mu$ strain and the signal contains components up to 10 kHz, the minimum bandwidth required for the system is 120 kHz. A system signal to noise improvement of 5.2 dB could be realized by using a standard FM receiver with a 150 kHz bandwidth.



## DATA RECOVERY CONSOLE

The primary function of the data recovery console is to recover in real time, the complete FM broadcast data stream (block diagram shown in Appendix B, Figure 1). The FM data signal is received, decoded and the resultant analog data is recorded on tape, displayed on an oscilloscope and shunted into an A/D converter to be used by the Microprocessor-Enhanced Display System (MEDS). The real-time oscilloscope display of each channel indicates the state of each strain gauge, assuring early detection of any erratic gauge behavior. A further discussion of the MEDS system is given in Appendix B pages 31 through 33.

The data recovery console fabrication is 90% complete and most of the circuits have been electrically tested. Initial testing indicates the necessity for some sync circuit redesign, with some associated timing circuit modifications. The MEDS is currently under development at the Biomechanics Research Section Division of Orthopedic Surgery, UCLA. The UCLA MEDS hardware is underwritten entirely by donations received through the efforts of patients who have received total-joint replacement at UCLA.

## IMPACT TO INDUSTRY

The received telemetry data will be the first in-vivo loading information from a total hip replacement. Even if only one patient implantation were to be achieved, the information will be invaluable. Direct measurement of hip force with walking aids, casts and modified gait patterns will give relative measure of the effectiveness of these techniques. Validation of mathematical models of the hip using force plate inputs will also be a possibility for each individual patient. This data will be of tremendous value in understanding the mechanical forces responsible for prosthetic loosening and fracture. The direction and magnitude of acetabular cup wear is also of clinical interest. Wear measurement by serial comparison of patient x-rays is plagued by many sources of error, one of which is the unknown direction of wear in any given patient implantation. Our in-vivo measurements of the force vector will indicate the contact region within the cup and also provide the contact force magnitude, its duration and its frequency of occurrence. This information is necessary to establish accurate input levels for laboratory wear simulations. The information obtained will also provide a sound experimental basis for formulating recommendations for postoperative management of total joint replacement patients. Leading implant manufacturing firms such as Zimmer Co., Howmedica Co., and DePuy Co., have already expressed interest in the program.

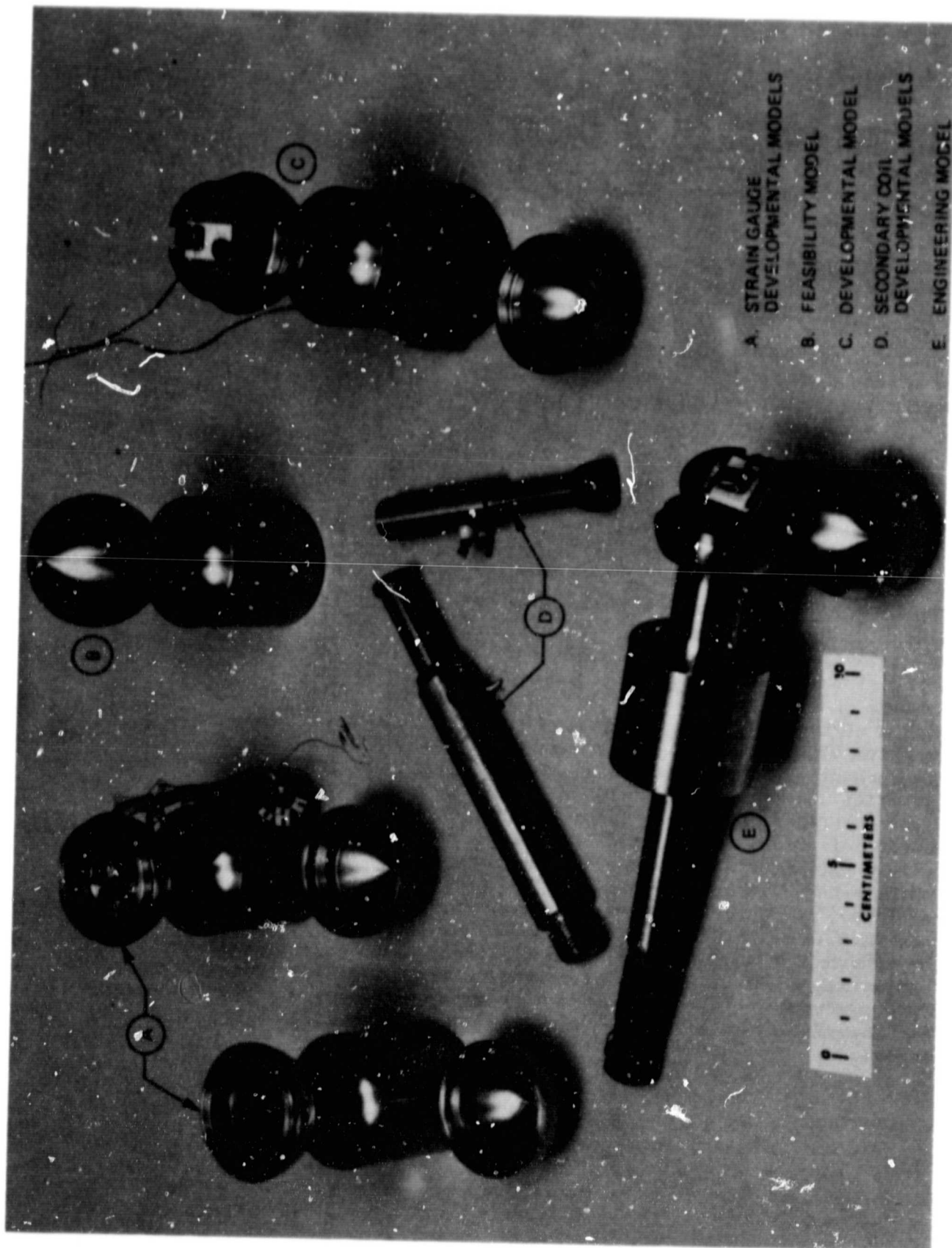


Figure 1. Hip Replacement Hardware Developments

Table 1. Hardware and Tests Performed

	Full TIM Transmitter	Full Strain Gauging	Load Tests	Power Induction Tests	Full RF & Air Link Test	Vibration Test	Hermetically Sealed	RF Freq. & Electrical Tests
Laboratory Breadboard	Yes	No	No	Yes	No	No	No	Yes
Strain Gauge Developmental Models	No	No	Yes	Yes	No	No	No	No
Feasibility Model	Yes	No	No	No	No	No	Yes	Yes
Developmental Model	Yes	Yes	Yes	Yes	Yes	No	No	Yes
Secondary Coil Developmental Models	No	No	No	Yes	No	No	No	No
Engineering Model	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes

Table 2. Typical Biotelemetry System  
Electrical Performance Parameters

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RF OUTPUT

Nominal Power	0.6 mW $\pm$ 0.2 mW
Frequency center	89 MHz
Frequency settability	$\pm$ 100 kHz
Frequency stability	$\pm$ 13.5 PPM/ $^{\circ}$ C

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MODULATION

Type	PAM/FM
Channels	6 data, 4 calibration
Channel width	500 sec
Frame rate	200 Hz
Sensitivity	94.5 Hz/ $\mu$ strain
Range	$\pm$ 505 $\mu$ strain
Linearity	$\pm$ 2.1 $\mu$ strain

---

DC (INTERNAL)

Power	8V, 6 mA
Voltage regulation	$\pm$ 0.13%
Ripple voltage	100 mV RMS

---

INDUCTION (EXTERNAL)

Frequency	250 kHz $\pm$ 5 kHz
DC power	10 Watts Max

---

RECEIVER

Frequency range	55 - 260 MHz
RF bandwidth	500 kHz
Video bandwidth	100 kHz
Noise figure	11.5 dB

---

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- 6) Carlson, C. E.: A Radio Telemetry Device for Monitoring Cartilage Surface Pressures in the Human Hip, IEEE Trans. Biomed Engr 21-4, July 1974.

**APPENDIX A**

**BIOTELEMETRY FROM A TOTAL HIP REPLACEMENT PROSTHESIS**

# BIOTELEMETRY FROM A TOTAL HIP REPLACEMENT PROSTHESIS<sup>\*</sup>

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Jet Propulsion Laboratory, Pasadena, California

Keith L. Markolf, Ph.D.  
Jack Willis  
University of California, Los Angeles, California

## INTRODUCTION

Total hip replacement is rapidly gaining in popularity among orthopaedic surgeons. In 1976 approximately 90,000 hips were implanted in the United States. Patient costs for these implants are estimated to be 100 million dollars per year. The two year failure rate is approximately 5%, mainly due to loosening of the femoral component (1). This failure rate is expected to increase as these units are implanted into a younger, more physically active patient population.

Mechanical complications of prosthesis breakage, excessive wear of the bearing components and loosening of the prosthetic components are directly related to the transmission of force across the joint. The dynamic or impact nature of these loads are also important for predicting joint performance. Adequate data on these vital subjects are lacking in the literature.

One method of estimating joint forces involves calculations based upon mathematical idealizations of joint geometries and material properties, using input loadings derived from force plate data. Paul (2) used such a model to estimate the force in the normal hip joint. The errors in such calculations are not known since dynamic effects due to the musculature can only be estimated in analytical calculations.

There are only two published studies dealing with direct in-vivo measurement of human joint loading. Rydell (3) instrumented two modified Moore hemiarthroplasty prostheses which were implanted into the hips of two patients. The hollow neck of each device contained strain gauges which were bonded to the inner surface. The wires to the gauges were housed within a metal cable which was left beneath the fascia until six months after surgery, at which time it was brought out through the skin and connected to recording equipment. Valuable measurements of the hip force components and friction between the metal head and acetabular cartilage were recorded, but the usefulness of his device was limited by the relatively short period of time available for data acquisition due to potential infection and skin interface problems from the instrument cable. Availability of a telemetry system would have been a distinct advantage, but the state of the art of microelectronics twelve years ago was not sufficiently advanced for this application.

Frankel and Burstein (4) were the first investigators to utilize an implantable biotelemetry system to measure joint loading. A specially designed hip nail was hollowed out in the plate portion to receive

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<sup>\*</sup> Biotelemetry IV, pp. 195-198, 1978  
Eds.: H. S. Klewe and H.P. Kimmich

relatively bulky discrete electronic components which were powered by miniature batteries. At least three such devices were implanted in patients who had sustained femoral neck fractures. As the fractures healed, the proportion of the load carried by the hip nail diminished. The useful period of data acquisition was limited to from nine to twelve months by the shelf life of the batteries. The information gained was of limited use for total joint replacement design since the patients were elderly, only limited weight bearing was allowed, and the total joint load could not be measured since part of the load was carried by the implant and part by the fracture which healed as time progressed.

A biotelemetry system suitable for implantation into a specially designed total hip femoral component has been developed in order to record in-vivo loading data for a variety of patient activities. A sketch of the proposed femoral component is shown in Figure 1.

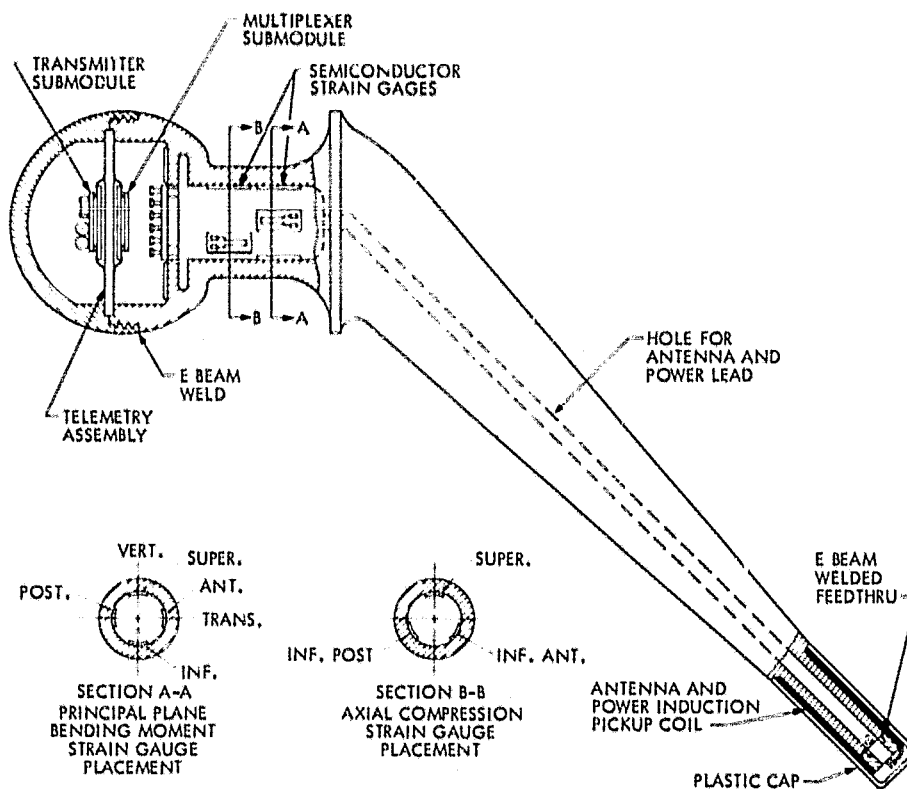


Figure 1. Hip Joint Prosthesis with In-Vivo Telemetry System

#### DESCRIPTION

Mechanical. The prosthesis is machined from work hardened 316 LVM stainless steel for strength, machinability, biocompatibility and welding properties. The latter is important since the prosthesis itself forms the outer hermetic cavity via E-beam welds at the ball and stem tip openings. The antenna and power induction wires are carried through the tip seal by a specially designed feedthrough whose components are platinum, glass and 316 stainless.



Semiconductor strain gauges are bonded to the inner surface of the prosthetic neck as shown in Figure 1. The vertical and transverse pairs measure bending moments about those axes, while the axial compression component is derived from the three gauges at section B-B. Each of these gauges is paired with an unstressed gauge located on the undercut, zero stressed, ledge in the ball. A common pair of resistive elements complete the other two elements of all bridge circuits.

Electrical. The electronic circuit design has been developed at UCLA by research assistants (5, 6, 7) under the direction of authors Markolf and Willis since 1973. The system design is similar to that reported by Carlson (8) in that it uses a time multiplexed, PAM/FM telemetry system with power supplied via induction coupling. JPL reviewed the

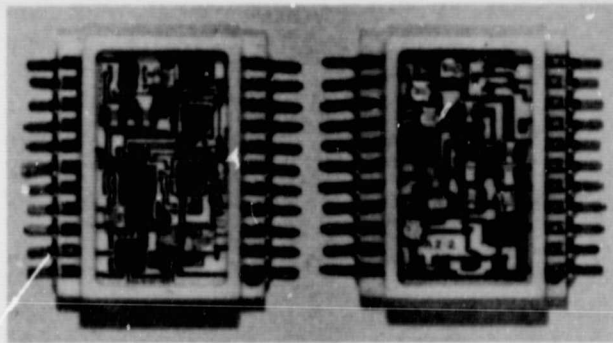


Figure 2. Multiplexer (left) and Transmitter Submodules

circuit design on the basis of the project criteria; namely, long life, reliability, low power consumption, stability and capability to be packaged into the required volume; and concluded that it met these requirements. Hence JPL's efforts have been aimed at the application of hybrid microcircuit packaging techniques similar to those developed for the NASA Standard Transponder (NST) Program as well as the mechanical packaging.

A major factor in the selection of the UCLA circuit design was the use of commercially available IC's as opposed to the use of custom LSI due to the extreme reliability requirements. A second factor was the fact that the NST hybrid technology would accommodate the seven IC's, four diodes, one transistor, seven capacitors and 17 resistors in two ceramic, thin film submodules as shown in Figure 2.

Power Induction. The power required for the strain gauges and the electronic circuit of the implanted telemetry transmitter will be induced from an external R.F. power generator. This generator operates from an 18 volt 1 amp battery supply and produces R.F. power at approximately 400 kHz. The output of the oscillator is fed from the belt mounted package via a transmission line to a coil worn around the thigh of the patient during clinical monitoring. This coil consists of 3 wire bundles each of 23 turns of litz wire, 8 inches in diameter, mutually coupled to the tapped coil of the oscillator which consists of 500 turns of 36 gauge teflon coated platinum wire. The voltage developed across the pickup coil is approximately 14 volts and, after being bridge rectified and regulated, supplies the required 8 volts at 15 mA.

Performance. Each 5 ms telemetry frame starts with a plus, minus full scale and zero, sync and calibration sequence, followed by the verticle and transverse moments, the three axial measurements and a repeat of the two moments (10 channels). Hence, the sampling frequency of the moment measurements is 400 Hz while that of the axial compression

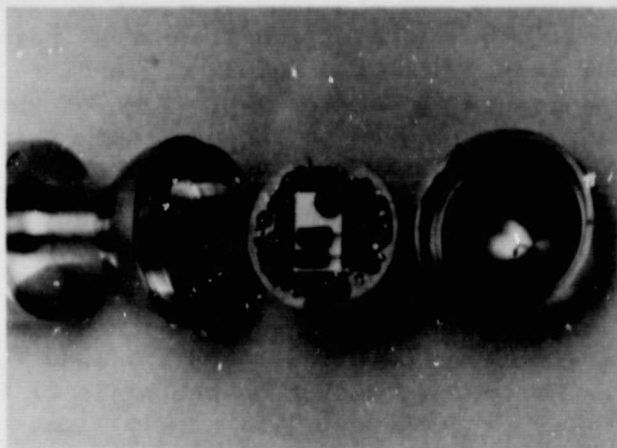


Figure 3. Exploded view of Telemetry Module and Prosthesis compatible with installation in a 32 mm prosthetic ball.

is 200 Hz. The transmitter operating at 90 MHz has a 1 mW output with a modulation linearity of better than 1% for carrier deviations up to  $\pm 75$  kHz. System SNR of the feasibility model system shown in Figure 3 has been measured at greater than 50 dB at 5 m.

#### CONCLUSIONS

This biotelemetry system is still under development and hence will certainly undergo further metamorphosis. Since the feasibility model ball diameter is 38 mm, near term goal is to reduce the mother board diameter to be compatible with installation in a 32 mm prosthetic ball.

#### ACKNOWLEDGEMENTS

The authors wish to acknowledge the contributions of R. Postal, J. Rice, and D. Lo Giurato at JPL.

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## APPENDIX B\*

### GRANT APPLICATION

\*The pagination shown in Appendix B indicates the original pagination of the document and has not been changed to reflect the pagination of the present report. Pages 3 through 16 and 39 are not included from the Grant Application.

SECTION I

DEPARTMENT OF  
HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE

LEAVE BLANK

TYPE	PROGRAM	NUMBER
REVIEW GROUP		FORMERLY
COUNCIL (Month, Year)		DATE RECEIVED

GRANT APPLICATION

TO BE COMPLETED BY PRINCIPAL INVESTIGATOR (Items 1 through 7 and 15A)

1. TITLE OF PROPOSAL (Do not exceed 53 typewriter spaces)

Total Hip Implant - Histiometry.

2. PRINCIPAL INVESTIGATOR

2A. NAME (Last, First, Initial)

Markolf, Keith L.

2B. TITLE OF POSITION

Adj. Asso. Professor Ortho/Biomech.

2C. MAILING ADDRESS (Street, City, State, Zip Code)

The Regents of the University of Calif.  
University of California  
405 Hilgard Avenue  
Los Angeles, Ca. 90024

3. DATES OF ENTIRE PROPOSED PROJECT PERIOD (This application)

FROM

January 1, 1981

THROUGH

December 31, 1982

4. TOTAL DIRECT COSTS RE-  
QUESTED FOR PERIOD IN  
ITEM 3

5. DIRECT COSTS REQUESTED  
FOR FIRST 12-MONTH PERIOD

6. PERFORMANCE SITE(S) (See Instructions)

UCLA - Los Angeles, Ca. 90024  
A) Biomechanics Research Section,  
Rehabilitation Center.  
B) School of Medicine  
Center for the Health Sciences

2D. DEGREE

Ph.D.

2E. SOCIAL SECURITY NO.

2F. TELEPHONE AREA CODE TELEPHONE NUMBER AND EXTENSION

213 825-6341

2G. DEPARTMENT, SERVICE, LABORATORY OR EQUIVALENT  
(See Instructions)

Surgery

2H. MAJOR SUBDIVISION (See Instructions)

School of Medicine

7. Research Involving Human Subjects (See Instructions)

A. ☐ NO B. ☐ YES Approved: \_\_\_\_\_ Date \_\_\_\_\_

CXXX YES - Pending Review

8. Inventions (Renewal Applicants Only - See Instructions)

A. ☐ NO B. ☐ YES - Not previously reported

C. ☐ YES - Previously reported

TO BE COMPLETED BY RESPONSIBLE ADMINISTRATIVE AUTHORITY (Items 8 through 13 and 15B)

9. APPLICANT ORGANIZATION(S) (See Instructions)

The Regents of the University of Calif.  
University of California  
405 Hilgard Avenue  
Los Angeles, Ca. 90024

11. TYPE OF ORGANIZATION (Check applicable item)

☐ FEDERAL ☒ STATE ☐ LOCAL ☐ OTHER (Specify)

12. NAME, TITLE, ADDRESS, AND TELEPHONE NUMBER OF  
OFFICIAL IN BUSINESS OFFICE WHO SHOULD ALSO BE  
NOTIFIED IF AN AWARD IS MADE

Philip E. Costic  
Contracts and Grants Office  
UCLA  
Los Angeles, Ca. 90024

Telephone Number (213) 825-0696

10. NAME, TITLE, AND TELEPHONE NUMBER OF OFFICIAL(S)  
SIGNING FOR APPLICANT ORGANIZATION(S)

Philip E. Costic  
Contracts & Grants Officer

Telephone Number (213) 825-0628

13. IDENTIFY ORGANIZATIONAL COMPONENT TO RECEIVE CREDIT  
FOR INSTITUTIONAL GRANT PURPOSES (See Instructions)

School of Medicine

14. ENTITY NUMBER (Formerly PHS Account Number)

1956006143A1

15. CERTIFICATION AND ACCEPTANCE. We, the undersigned, certify that the statements herein are true and complete to the best of our knowledge and accept, as to any grant awarded, the obligation to comply with Public Health Service terms and conditions in effect at the time of the award.

SIGNATURES (Signatures required on original copy only. Use ink, "Per" signatures not acceptable)	A. SIGNATURE OF PERSON NAMED IN ITEM 2A	DATE
	B. SIGNATURE(S) OF PERSON(S) NAMED IN ITEM 10	DATE

PHS-398 (Formerly NIH-398)  
Rev. 1-73

This application does not involve recombinant DNA

## SECTION I

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE

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PROJECT NUMBER

## RESEARCH OBJECTIVES

## NAME AND ADDRESS OF APPLICANT ORGANIZATION

The Regents of the University of California, University of California  
105 Hilgard Avenue, Los Angeles, Ca. 90024

## NAME, SOCIAL SECURITY NUMBER, OFFICIAL TITLE, AND DEPARTMENT OF ALL PROFESSIONAL PERSONNEL ENGAGED ON PROJECT, BEGINNING WITH PRINCIPAL INVESTIGATOR

Keith L. Markolf, Ph.D., [REDACTED] Adjunct Asso. Professor, Surgery, Ortho/Biomechanics  
Harlan C. Amstutz, M.D., [REDACTED] Prof. & Chief, Orthopaedics

## TITLE OF PROJECT

Total Hip Implant - Biotelemetry

USE THIS SPACE TO ABSTRACT YOUR PROPOSED RESEARCH, OUTLINE OBJECTIVES AND METHODS, UNDERSCORE THE KEY WORDS (NOT TO EXCEED 10) IN YOUR ABSTRACT.

This research proposal represents a collaborative effort between the Biomechanics Research Section of the UCLA Division of Orthopedic Surgery and the California Institute of Technology Jet Propulsion Laboratory. Our express objective is the design and development of a special total hip femoral component which will contain within it a miniaturized biotelemetry system capable of broadcasting signals received from strain gauges mounted within the neck of the prosthesis. The prosthesis will be inductively powered by an external coil worn around the thigh of the patient, thereby eliminating the need for internal batteries. These strain readings will be analyzed by computer and combined to display the three force components and the magnitude and orientation of the resultant force vector acting on the head of the prosthesis. The present proposal is directed toward the design of the implant, refinement of the telemetry system performance, development of the power induction system, assembly of a data recovery system, a mechanical testing program designed to assure the structural integrity of the implant and finally a leak-test program to assure the hermeticity of the total system. In vivo loading data of an implanted total joint prosthesis is not presently available in the literature. The peak loads and the impact durations are important for analysis of prosthetic loosening, acrylic fracture and prosthesis breakage. Such data will find direct application for fatigue analysis of implant failures, programmed input into total joint simulators and input into finite-element models of implanted total joints. In vivo loading data will provide an objective clinical basis for general recommendations of post-operative patient activities, such as proper use of walking aids, rising and sitting, climbing and descending stairs and ramps, etc. This data will also allow validation of existing mathematical models of the hip, and lead to refinements in the assumptions made in their construction, thereby leading to important advances in the state of the art of biomechanical modeling of the musculoskeletal system.

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## TOTAL HIP IMPLANT - BIOTELEMETRY

### RESEARCH PLAN

This research proposal is a collaborative effort between the Biomechanics Research Section of the Division of Orthopedic Surgery, University of California at Los Angeles (UCLA) and the California Institute of Technology Jet Propulsion Laboratory (JPL), Pasadena, California.

## A. SPECIFIC AIMS

The express objective of this proposal is the design and development of a special total hip femoral component which will contain within it a miniaturized biotelemetry system capable of broadcasting signals received from strain gauges mounted within the neck of the prosthesis. The prosthesis will be inductively powered by an external coil worn around the thigh of the patient, thereby eliminating the need for internal batteries. These strain readings will be analyzed by computer and combined to display the three force-components and the magnitude and orientation of the resultant force-vector acting on the head of the prosthesis. This information will vastly improve our understanding of hip biomechanics, provide information of use to clinicians in post-operative recommendations to their patients - thereby enhancing the overall quality of their medical care - and lead to important advancements in implant design. It is not our objective in this proposal to provide prostheses for actual patient implantation; this will be the goal of a follow-on proposal. The present proposal is directed towards the design of the implant, refinement of the telemetry system performance, development of the power-induction system, assembly of a data-recovery system, a mechanical testing program designed to assure the structural integrity of the implant and finally a leak-test program to assure the hermeticity of the total system. All test data gathered from this project will be presented to the UCLA Human Use Committee for their consideration and approval before proceeding into the patient implantation phase of the program.

Due to volume requirements for the strain gauges and telemetry module, the implant will be somewhat larger than many existing models of conventional human hip-replacements, and will utilize a 35 millimeter-diameter ball. Extensive in vitro testing has been selected as opposed to animal implantation. This is due to practical limitations in the selection of a suitable experimental animal. Even though a large experimental animal such as one of the pongids (the orangutan, the chimpanzee or the gorilla) could possibly accept our human-size implant, assuming surgical techniques and instrumentation could be developed for a total hip operation on the animal, dissimilarities in musculature, gait and activity would produce implant-loadings different than those expected in the human. Such a study would therefore not validate its safety for human application. In contrast, there is a great body of practical knowledge of current human hip-replacement design-configurations. The wide range of sizes and shapes of implants currently available along with their performance records gives us practical guidelines for the modification of existing design-concepts for our specific application. It is this approach that we have chosen to follow, and our efforts will be directed towards extensive laboratory testing to satisfy ourselves (and the UCLA Human Use Committee) that our implant will perform as designed.

1. Twelve multiplexing and twelve transmitter submodules will be fabricated, bench-tested and subjected to environmental and accelerated life-tests to assure system reliability. In addition, twelve complete telemetry assemblies will be prepared for insertion into prototype prostheses for mechanical testing.
2. A special femoral component utilizing our 35 millimeter ball-and-neck load-cell configuration will be designed and twelve prototype models machined from cold rolled 316 stainless steel will be subjected to mechanical tests to assure structural integrity and accuracy of calibration.
3. The power-induction system design will be modified to improve stability and efficiency, and to reduce the size and weight of the external coil and battery pack.
4. Hermeticity of the sealed femoral components will be verified by leak-tests before, during and after fatigue-testing of prototype units. Two units will have simulated breaks in the stem and ball regions to evaluate the secondary seal system.
5. Biocompatibility of the prosthesis coil located at the stem tip will be verified by implantation into dogs and subsequent histological examination.
6. A data-recovery system will be developed to process and display the telemetered strain gauge information in a format which is convenient for clinical interpretation.



## B. SIGNIFICANCE

In 1976, over 100,000 total hip-replacement operations were performed in the U.S.A. alone<sup>10</sup>. Symptomatic loosening have been reported to vary from 3 to 54 per cent, with onsets ranging from as early as six months, increasing with time after operation<sup>11,12,13,14,15,16,17,18,19,20,21,22</sup>. X-ray evidence of femoral component loosening has been noted to be in excess of 20 per cent in published series from UCLA<sup>17</sup> and the Mayo Clinic<sup>4</sup>. Beckenbaugh<sup>4</sup> reported failures due to prosthetic loosening with subsidence in up to 24 per cent of patients in as little as seven years. Chandler<sup>8</sup> noted a failure-rate of 54 per cent after only five years in patients under thirty years of age. Femoral component stem breakage has been reported to vary from .23 to 8 per cent<sup>3,4,14,18,23,27</sup>. These numbers can only grow as total hips are implanted into increasing numbers of younger, active patients who have expectations of increased levels of performance from their diseased joints. In light of these alarming statistics, it is astonishing how little is known about the dynamic forces acting on the hip joint and their relationship to clinical complications of the surgical procedure.

It has long been recognized by clinicians that the forces in the hip joint can be high for certain activities. A simple static analysis of the upper torso during stance phase of gait shows the forces to be two to three times body weight. However, few loadings of the hip are static in nature, and analyses based upon anatomic simplifications are most certain to be in error. The multitude of possible patient movements makes analysis of all activities of interest impractical; hence, new techniques to study hip forces are needed. The long-term clinical success of total joint replacement depends upon the ability of the bone-implant system to withstand the forces applied to it. Mechanical complications of implant breakage, cement fracture, skeletal loosening and component wear are directly related to the transmission of force across the joint. The dynamic or history over time of these forces are also important for predicting implant performance. Accurate data on these vital subjects are lacking in the literature.

## CALCULATION OF JOINT FORCES

One method of estimating joint forces involves calculations based upon mathematical idealizations of joint geometries, material properties and assumed loading conditions. Morrison<sup>25</sup> calculated forces developed in the knee joint during gait from force-plate data. The maximum joint force calculated in the knee for level walking was two to four times body weight. Smidt<sup>30</sup> calculated forces in the knee joint for maximum isometric contractions in various positions of knee flexion. The compression force at the tibial-femoral joint ranged from 0.4 to 3.4 times body weight. It is worthwhile to compare calculated forces present at the knee and hip during gait. Paul<sup>26</sup>, using a force-plate analysis similar to Morrison, calculated maximum loads in the hip of 2.3 to 5.8 times body weight. More recently, Johnston<sup>31</sup> has calculated hip joint forces from a new three-dimensional mathematical model which includes advanced representations of the hip musculature and geometry. Footplate reactions, kinematic data and mass distribution of the body segments are combined into a Newtonian model of the lower extremity to calculate the inter-segmental resultant forces and moments. This model was used to evaluate the effects of surgical placement and femoral component geometry on the resultant hip load.

The joint and ligament forces calculated from these studies are the result of a mathematical idealization of joint anatomy. The force values quoted are only approximate and the errors involved in the analysis have not been estimated. Clearly, in vivo data would contain dynamic effects, including the musculature which can only be estimated in analytical calculations.

## IN VIVO MEASUREMENTS OF JOINT FORCES

There are two major studies dealing with direct in vivo measurement of human hip loading. Rydell<sup>28</sup> instrumented two modified Moore hemiarthroplasty prostheses which were bonded to the inner surface. The wires to the gauges were housed within a metal cable which was left beneath the fascia until six months after surgery, at which time it



was brought out through the skin and connected to recording equipment. Valuable measurements of the hip force components and friction between the metal head and acetabular cartilage were recorded, but the usefulness of his device was limited by the relatively short period of time available for data acquisition due to potential infection and skin interface problems from the instrument cable. Availability of a telemetry system would have been a distinct advantage, but the state of the art of micro-electronics fifteen years ago was not sufficiently advanced for this application.

Frankel and Burstein<sup>15</sup> were the first investigators to utilize an implantable biotelemetry system to measure joint loading. A specially designed hip nail was hollowed out in the plate portion to receive relatively bulky discrete electronic components which were powered by miniature batteries. At least three such devices were implanted in patients who had sustained femoral neck fractures. As the fractures healed, the proportion of the load carried by the hip nail diminished. The useful period of data acquisition was limited to from nine to twelve months by the shelf life of the batteries. Hip loads for a variety of patient-related activities were recorded and many well-established axioms of post-operative patient management have been questioned in view of their findings.

Carlson<sup>6,7</sup> described a 16-channel multiplex FM biotelemetry system suitable for implantation within the hollow head of a modified Moore hemiarthroplasty. The purpose of this device was not to measure hip load directly, but rather the pressure distribution across the acetabular cartilage during in vivo loading conditions. For this purpose, fourteen miniature pressure transducers were located on the inner surface of the sphere. The system was designed to be powered by an external coil worn around the patient's limb, allowing transfer of RF energy into the implanted device to energize the strain gauge bridge circuitry. The system utilized modern integrated circuits specially designed for this application. Although their system is available for implantation, a suitable recipient has not yet been found.

#### THE JPL-UCLA TELEMETRY SYSTEM

Design of a practical radio telemetry system for artificial joint implant applications requires careful consideration and analysis of the following factors: system physical size, DC power consumption, number of desired channels of information, type of signal processing (modulation and multiplexing) to be employed, radiated frequency and RF power level, method of providing primary DC power, system complexity, system accuracy and stability, and reliability. In addition, considering economy and reliability of reproduction, the system should employ standard existing electronic components wherever possible. The most severe design constraints imposed by the above factors are the desired low DC power drain and small physical size. These conditions can be satisfied by using micro-power integrated active circuits, such as the Complementary MOS devices in the chip configuration, and employing hybrid techniques for system integration. In order to minimize possible noise problems, the transmitter output will employ FM modulation rather than AM. The RF frequency will be chosen to be within the 88 to 108 MHz band to allow signal detection and demodulation by means of a standard FM broadcast receiver. The time multiplexer unit for Pulse Amplitude Modulation contains a digital clock, counter and channel selector to provide sequential energizing of strain gauges. The counter and channel selector will consist of a single commercially C-MOS integrated circuit allowing up to ten channels of information. The principal advantage of this multiplexing scheme is the low power consumption achieved by the use of C-MOS circuitry and high resistance semiconductor strain gauges which are energized one at a time. Four of the ten channels will be used for synchronization and calibration, leaving six useful channels of information. The sampling rate of 200 Hz should provide more than adequate frequency response for the anticipated frequency spectrum of the prosthetic joint forces.

## IMPORTANCE

In vivo data for loading of an implanted total joint prosthesis is not presently available in the literature. Such data will be invaluable for a variety of practical considerations:

- a. The peak loads and the impact durations are important for analysis of prosthetic loosening, acrylic fracture and prosthesis breakage. Such data would find direct application for fatigue analysis of implant failures, programmed input into total joint simulators and input into finite element models of implanted total joints.
- b. In vivo loading data will provide an objective clinical basis for general recommendations of post-operative patient activities, such as proper use of walking aids, rising and sitting, climbing and descending stairs and ramps, etc. This information will be of particular benefit to the patient receiving the implant.
- c. Existing mathematical models of the hip, such as developed by Crowninshield<sup>13</sup> and associates, rely on force-plate input data to compute muscle and joint forces. In vivo hip joint telemetry provides an excellent technique for validation of these models. A patient with an implanted hip prosthesis could walk on the force plate and the in vivo readings obtained from bio-telemetry could be compared to the computed force profile from the model. This will lead to refinements in assumptions made in construction of the model, and to important advances in the state of the art of biomechanical modelling of the musculoskeletal system.
- d. The direction and magnitude of acetabular cup wear is of clinical interest. Wear measurement by serial comparison of patient x-rays is plagued by many sources of error, one of which is the unknown direction of wear in any given patient implantation. Our in vivo measurements of the force vector will indicate the contact region within the cup and also provide the contact force magnitude, its duration and its frequency of occurrence. This information is necessary to establish accurate input levels for laboratory wear simulations.

The proposed telemetry system will have a number of distinct advantages for this particular application.

- a. Reliance on batteries has been eliminated by induction powering in the implant, thus assuring long-term retrieval of information from the patient.
- b. The miniature electronics utilizes recent state of the art advances in optimized hybrid integrated circuit design.
- c. The JPL-UCLA system will be significantly smaller and will consume far less power than any telemetry system previously developed for orthopedic applications.

## SYSTEM DESCRIPTION

A biotelemetry package small enough to fit into the hollow stainless steel ball of a total hip joint replacement prosthesis to allow in vivo measurements of loads across that joint has been designed and various models fabricated and evaluated<sup>5</sup>. The ball size, which initially was 38 millimeters in diameter, has been reduced to 35 millimeters on the recommendation of Dr. Amstutz. With this size ball, the head-neck ratio is comparable to other designs in clinical use, and the risk of component dislocation will be reduced. Although further reductions in ball size may be possible in the future, reductions in the neck size are far more difficult to achieve due to accompanying decreases in strength and increased difficulties of strain gauge placement and wiring within the central neck region. The telemetry unit is designed for very long life with the use of electronics packaging technologies inherited from those used in deep space applications. No batteries requiring replacement are used, but rather it is powered only during clinical monitoring sessions by low frequency RF induction via a cuff temporarily worn by the patient around the top of the thigh. In the laboratory setting, the induction oscillator will be powered by a thin cord attached to an electrical supply outlet. A portable battery pack is also planned for field studies.

The forces of interest are measured by miniature strain gauges bonded inside the prosthesis neck, formatted and conditioned by the multiplexer submodule, and transmitted out of the body via the FM antenna at the tip of the prosthesis stem. The signals can then be detected by an external radio receiver, located nearby and fed into a decoding and display system for readout and final interpretation.

Figure 1 is a functional block diagram of the telemetry system. It is separated into the internal telemetry package and the external power induction, data recovery and display instrumentation. The internal elements function to commutate the strain gauges at a 200 Hz rate by means of a decade counter synchronized by a 2000 Hz clock. The counter controls a 10-channel FET switch assembly which connects the strain gauges sequentially to a DC amplifier. The amplifier modulates a voltage controlled oscillator to frequency modulate a transmitter with frequency swings proportional to strain gauge outputs. The external FM receiver output is synchronized to the internal multiplexer such that the channel outputs are decoded and measured for recording on oscillographic or magnetic tape recorders. Calibration pulses precede the data pulses and consist of a full scale (sync) voltage in each polarity followed by the zero level. The sync signature is used by the data recovery system to identify the data channels. The calibration channels identify the full scale and zero output levels. Displays for both real time and recorded playback functions are provided by the data recovery and display consoles.

A sectional view of the instrumented prosthesis is shown in Figure 2, and illustrates the placement of the various components mounted within the unit. The stem configuration is shown for display purposes only; this geometry is not the planned version for the prototype implants. Eight active strain gauges, spaced 45 degrees apart in the highest stressed area around the inner periphery of the neck, provide the means of measuring the vertical and transverse moments and axial force data (along the axis of the neck) required to resolve the magnitude and direction of the force vector at the joint. All three components of the resultant femoral head force can be measured with respect to the prosthesis ball and neck. Orientation with respect to the patient's skeleton will be determined by x-rays.

Four more gauges are used than the minimum number necessary to provide the data required. This is done to provide redundancy such that any one gauge or telemetry channel can fail and with some minor reprogramming of the data recovery format normal operation can be restored. Since semiconductor strain gauges are highly temperature-sensitive they are paired together in order to compensate for this effect. The pairs of vertical and transverse gauges are connected together to provide direct measurements of the vertical and transverse moments. In order to make the axial force measurement and to provide the redundancy mentioned, each of the axial gauges is paired with a

mechanically isolated dummy gauge for temperature compensation and its data is telemetered out on separate channels. Even though data from only two diametrically opposed axial gauges is required to resolve the axial force, under normal operation all four axial gauges are algebraically summed for better accuracy. In the event of a failure of one of the moment gauges or channels, the axial channels can be summed in adjacent pairs and differenced with opposite pairs to reconstruct a moment measurement.

The telemetry assembly is mounted in the prosthesis ball which is sealed using electron beam (E-beam) welding. The stainless steel feedthrough at the stem tip is also E-beam welded and contains three platinum pins with glass insulation to provide the electrical interface to couple 1) the RF signal to the FM antenna and 2) the power induction pickup coil to the telemetry assembly. These hermetic seals are procured from Astroseal, a qualified manufacturer of space and biomedical quality electrical feedthroughs. The two-turn gold wire antenna and 738-turn pickup coil are wrapped around the stem tip and are protected with a plastic cap.

#### TELEMETRY ASSEMBLY

The telemetry assembly provides timing and multiplexing of strain gauge output data onto an FM transmitter carrier as well as conditioning of the induction power. The assembly is packaged into two hermetically sealed ceramic submodules using space technology techniques that allow reliable circuit miniaturization. A photograph of the multiplexer and transmitter submodules (unsealed) is given in Figure 3. Both submodules employ hybrid elements on an alumina substrate in a typical microstrip fabrication technology. The transmitter submodule contains a DC amplifier, VCO FM transmitter, power induction rectifier-bridge and voltage regulator. Similarly, the telemetry multiplexer submodule consists of the clock, decade counter and FET switches. Both submodules are connected to an assembly circuit board using conventional solder techniques. The complete telemetry assembly, with sealed submodules attached to the assembly circuit board, is shown in Figure 4. The telemetry assembly was first built in discreet component form in 1977 and in miniaturized form suitable for a 38 millimeter ball in 1978. The assembly has recently been reduced in size to fit within a 35 millimeter ball. An auxiliary terminal board, located at the intersection of the ball and the neck, has also been included to allow both trim and gain-set resistors to be included for the six active channels. Only minor modifications have been made to the submodules since the original concept and those were due to changes necessitated by data channel reassignment, and the use of a more efficient voltage regulation chip.

#### PRELIMINARY LOADING TESTS (STRAIN MEASUREMENTS)

Of prime importance is to assure that overall telemetry system sensitivities along with measurement resolution and accuracies will be sufficient to meet clinical data recovery requirements. Static stress tests at JPL of a mechanical model prosthesis ball and neck region complete with strain gauges and a telemetry assembly have shown that load components can be reconstructed from telemetered output data with an uncertainty of less than 9 per cent. Figure 5 shows a sectional view of an instrumented mechanical model of the prosthesis ball and neck regions, while Figure 6 is a photograph showing the placement of the semiconductor strain gauges in the neck area inside the unit. In this earlier model six active gauges are attached directly to the inner neck along with six dummy gauges attached for thermal tracking and mechanical isolation. For the stress tests the prosthesis was mounted in a test fixture that allows loading to be applied at various roll and tilt angles. A pictorial view of the fixture configuration for a 30 degree tilt position is illustrated in Figure 7, which also includes a diagram of strain gauge locations at that time. The laboratory test set showing a prosthesis under load in a 90 degree tilt position is shown in Figures 8 and 9. Loads are applied to the prosthesis through a load cell extension bar which eliminates torsion

between the hydraulic ram and load cell. Results from earlier tests performed without the torsion bar gave erroneous gauge output readings caused by inconsistent load direction. For the 30 degree tilt test, loads were applied to the prosthesis in 200-lb increments from 0 to 1000 lbs. Results of the six telemetered gauge outputs were processed with a computer/plotter program and are given in Figure 10.

Near the conclusion of the planned series of static stress tests on the developmental model prosthesis the force controller on the MTS test machine was inadvertently switched to an open loop configuration and the unit was overloaded. The maximum force applied before control was restored reached 5100 lbs and resulted in a permanent deflection of the ball and neck region of 3.5 degrees from the original axis of symmetry. This 'overload test' therefore establishes a measure of the factor of safety in the design.

#### PRELIMINARY TESTING OF THE POWER INDUCTION SYSTEM

The power induction system, designed to eliminate the need for internal batteries, has taken a significant design effort. A chronology of this effort began with the system design which was initiated at UCLA and then transferred to JPL at the end of 1979. The system component parts were then interfaced and tested to determine the power system stability and efficiency as well as adequacy in power transfer as a function of external/internal coil alignment and load impedance. The function of the power induction system is to furnish the secondary coil (internal) with sufficient energy to power the telemetry electronics for a varying range of oscillator induction coil (external) placement. The external oscillator coil is driven by a modified Hartley power oscillator and develops a high electromagnetic field that induces energy into a prosthesis-mounted secondary pick-up coil. Power transfer tests have been performed using several materials for the secondary coil. Performance using both platinum and gold wire is substantially less than the original UCLA design using copper. For human compatibility considerations, however, gold wire has been chosen as the best performer of non-copper materials tested.

Carlson<sup>7</sup> reported on a somewhat similar induction system, utilizing a ferrite core within the pickup coil to improve electromagnetic power coupling. The efficiency of his system was approximately 10 per cent at an input power level of 5 watts. These power levels are far too low to be of concern for tissue damage from radio frequency energy and heating effects. Schuder et al<sup>29</sup> studied power transmission through inductive coupling in the chest wall of the dog. They concluded that one hour per day operation at a power level of 1 kilowatt produced no apparent harmful effects. Only a slight temperature increase (3 degrees F) was recorded in tissues adjacent to the implanted coil. It should be noted that the power levels in these experiments were approximately 100 times greater than the levels proposed for our system.

Laboratory tests of a gold secondary coil wound on a simulated prosthesis stem were performed to determine system power transfer as a function of (1) vertical placement between external and internal coils and (2) telemetry circuit loading. A pictorial view of the component arrangement for the power induction system test is illustrated in Figure 11. Vertical placement of the secondary coil was varied about the induction coil centroid by raising and lowering a pulley mounted cord attached to the prosthesis. Horizontal placement tests were not performed since horizontal displacement about the centroid always results in increased power transfer. Results for the vertical placement tests are shown in Figure 12.

As shown, sufficient power transfer is obtained for vertical displacements of -2.5 to +1 inches for a maximum load of 1300 ohms and a minimum required telemetry voltage of 10.3 volts. The five load plots represent a range of telemetry circuit

loads that are dependent on telemetry component selection. Since the positional performance was acceptable, the next step was to power a fully operational prosthesis complete with secondary coil, telemetry transmitter, and antenna. As shown in Figure 13, the prosthesis was suspended in the center of the induction coil and placement tests were performed as before. The transmitted signal was received over an air link of 4 feet with receiver decoded data outputs presented on the scope as shown. Test results show the UCLA-designed power induction system is functional; however, marginal stability and low efficiency make it almost impractical to use as designed. The present method of winding the pickup coil directly on the stainless steel stem would require a battery pack (if portability is needed) that weighs about 10 lbs to be worn by the patient for 30 minutes of use. The excessive weight is required because of the low efficiency of the secondary coil, as it is wound on what would be considered an electrical short circuit. This can be improved by isolating the coil from the stem. Two alternative methods will be investigated. The first spaces the coil out from the tip metal with a dielectric form. The second concept involves winding the coil around a plastic extension of the stem tip, thereby eliminating the metal core which is drastically reducing the system efficiency. The induction oscillator system also requires some redesign to increase both its stability and efficiency. Additionally, the oscillator coil will be redesigned in cross sectional format from the toroidal bundle shown in Figures 11 and 12 to a thin cylindrical layup to better fit the recipient's thigh.

#### PRELIMINARY WELDING AND LEAK TESTS

Since the prosthesis shell represents the primary barrier between the recipient's tissue and body fluids and the internal electronic components, considerable design effort has been expended to insure that it 1) can be completely sealed with minimal effect on the internal electronics, 2) has sufficient strength not to break and 3) can be tested after assembly. Electron beam (E-beam) welding has been chosen as the best sealing method that satisfies all the above requirements. The E-beam weld is accomplished by rotating the prosthesis in an evacuated chamber while directing a high energy electron beam at the sealing joint. The weld sealing operation is accomplished in 4.5 seconds through one plus revolutions of the prosthesis. One of the main concerns of this process is the effect of heat produced by the electron beam on the internal electronic components. Another concern is the seal itself: how well it prevents fluids from entering the prosthesis. To assess the temperature effects on the internal electronics, several sample prostheses were instrumented for internal temperature profiles near the weld joint during sealing operations. It was determined that during sealing, temperatures beyond 0.125 inches from the joint do not exceed 121 degrees C which is well within the manufacturer's ratings for all components used. The temperature at the sensitive semiconductor strain gauges is not expected to exceed 50 degrees C during the processing which is well below the manufacturer's maximum operating temperature of 175 degrees C. A prosthesis with a telemetry assembly installed (see Fig. 5) was then sealed to assess the effects of E-beam welding on the telemetry functions. A comparison of measurements before and after sealing showed the welding operation had no effect on the telemetry electronics. A pre-sealing view of the prostheses electronics and scope-displayed telemetry output is shown in Figure 14.

The results of the hermeticity test after welding were as expected, with both the wet test and helium test showing no gross leakage, and the helium mass spectrometer measuring a fine leak rate of only  $5.9 \times 10^{-6}$  cc/sec He. The accepted leakage rate for space flight electronics is  $1 \times 10^{-6}$  cc/sec He, as specified by military standard 883B. After this initial set of leak tests, the ball was ground and polished, a process step required to remove external evidence of the welding step, and the functional electrical and gross and fine leak tests were repeated with similar results.

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## PRELIMINARY BIOCOMPATIBILITY TESTING

A stainless steel feedthrough (to be located at the stem tip) was mounted in a 316 LVM stainless steel capsule (shown in Fig. 15) and implanted into the back muscle of a dog. The dog was sacrificed at eight weeks and the capsule and surrounding tissue was removed for routine histological analysis. The outer surface of the metal capsule was surrounded with a thin fibrous membrane, as expected for 316 stainless steel which has high biocompatibility. Tissue had infiltrated the holes in the capsule wall and completely surrounded the platinum pins and gold wires. Histological examination revealed mature collagen fibers, fibroblasts and no evidence of acute inflammatory reaction in the vicinity of the platinum/gold junction. Pull tests of the gold/platinum weld on the pins opposite the gold coil are planned if the soft tissue can be successfully dissected free of the thin gold wires.

## D. METHODS OF PROCEDURE

1. Telemetry Performance Tests

In order to assess the degree of reliability of the internal electronic assembly, several groups of sealed submodules will be subjected to mechanical environmental tests as well as operational stress at elevated temperatures. A total population of twenty-four submodules (12 multiplexers and 12 transmitters) will be fabricated from parts known to be reliable either by burn-in or by manufacturer screening. Upon post-seal acceptance, the submodules will be subjected to environmental shock and vibration followed by an accelerated life test, performed by splitting the submodules into two groups and subjecting each group to operational temperature tests at two elevated temperatures separated by 50 degrees Celsius until sufficient failures have occurred to establish points on the Arrhenius curve. A performance evaluation of each submodule will follow shock and vibration tests and will also be performed at three-week intervals during accelerated life testing. These evaluations will be compared with the post-seal baseline performance for each submodule. Comparative parameter measurements will include: clock rate, multiplexer reference levels, RF frequency and output level, modulation sensitivity and voltage regulation.

Twelve complete telemetry assemblies (separate from the environmental test units) will be fabricated, tested and installed in prototype prostheses for mechanical testing. Ten of these have been scheduled into our static and fatigue loading programs. Two extra units will be available for substitution should electrical failure occur or for additional testing if required. The telemetry assembly consists of two sealed submodules attached to a mother board, strain gauges, and a balance/gain-set resistor board. Each submodule undergoes pre-seal and post-seal electrical evaluation, followed by a reliability burn-in and attachment to the mother board. The mother board is then interface-tested with the prosthesis shell, which contains the strain gauges and a welded feedthrough, for selection and installation of balance and gain-set resistors. After a final bench test, the system is calibrated in a static load test, after which resistance values are trimmed if necessary. The prosthesis is then E-beam welded and tested for hermeticity.

## TASK DIVISIONS

All fabrication, bench testing, accelerated life testing and assembly of the telemetry system components will be performed at JPL.

## 2. Implant Design and Testing

A detailed design of the head and neck of the prosthesis (the 'load cell' portion) has been completed (Fig. 5). Preliminary load calibration tests have demonstrated an error of less than 9 per cent between applied load and calculated load (via telemetered output) in the 0 to 1000 lb range at a 30 degree neck inclination from vertical. This design has gone through three iterations as modifications were required to provide broached flats within the neck for gauge mounting, changes in thread configuration to increase the outer wall thickness at the weld site, changes in the inner neck and shelf geometry to allow more room for active and dummy gauge placements, and finally a reduction of ball size from 38 to 35 millimeters, made possible by a re-design of the circuit layout board and pin connection terminals. Based upon our prior strain gauge studies of the necks of T-28, Charnley and Mueller prostheses<sup>21</sup>, and a stress analysis of the neck of the present configuration, we have conservatively estimated a factor of safety of two for our neck design; that is to say, the stresses at the base of the neck of our device (the anticipated point of failure) are approximately one-half those at a similar location of a commercially available implant. It is of interest that in the 30 degree loading configuration previously described, a load of 5100 lbs was required to produce a slight permanent bend in the neck (without fracture). We believe at this time that the head-neck portion of the implant is very close to its final design configuration. Attention will now be directed to the stem design. A number of strain gauge studies and finite element analyses have been performed on existing stem designs<sup>1,2,12,21,24,31,32,33</sup>. Anticipated strain levels and cross-sectional geometries for currently available implants will be used as guidelines for preliminary stem design parameters. We plan to eventually select patients for clinical trials who have relatively large femora, and will be able to readily accept a 35 millimeter femoral component. It should be noted that other component designs such as the Buchholtz and Aufranc prostheses also utilize 35 millimeter femoral balls. The stem size and shape will be compatible with the configuration of the femoral canal as determined from our prior anthropometric studies of the proximal femur<sup>20</sup>. Prototype stems will be machined from aluminum for trial fitting to a number of cadaver femora to assure adequate fit, space for acrylic, and proper clearance for the distal induction pickup coil at the stem tip.

The material we have selected for our prototype implants is cold-rolled 316 LVM stainless steel. The strength, availability and ease with which this metal can be machined and welded, along with its proven biocompatibility and wide clinical usage makes it an attractive material for our application. Initially, all prototype implants will be machined from bar stock in the UCLA orthopedic model shop. Once machining techniques have been developed for our twelve prototypes, we will eventually have the actual clinical implants fabricated by a commercial manufacturer. The management of Zimmer USA has indicated a desire to participate in the project for the clinical trials, and it is anticipated that they will work closely with us in later stages of the program. The Zimmer production facility has considerable experience in machining T-28 and Charnley prostheses from cold rolled 316 stainless steel. Although our stem will be larger in cross-section than these implants, to reduce the metal stresses, we do not anticipate any additional difficulties in manufacture.

A variety of mechanical tests are planned for the twelve prototype implants. These tests are designed to validate our final design configuration and to demonstrate its clinical safety. Our mechanical testing will require jigs and fixtures for mounting the implant to the test machine. Two types of support configurations are envisioned. The stems of the implants will either be gripped in an acrylic mould or cemented into fresh cadaver femora, which in turn will be mounted and gripped in the test machine. In our static and fatigue loading tests on T-28 and surface replacement prostheses, we have developed techniques for potting the femur in acrylic cement and testing in



a saline-filled test chamber (Fig. 16). This technique has proved successful for fatigue testing to 20 million cycles at load levels up to 700 lbs. These testing techniques will be modified for the present study.

#### CALIBRATION AND DEMONSTRATION (3 UNITS)

Three prototypes will contain full gauging and telemetry and will be powered inductively, but will not be welded. These units will be mounted in fixtures for extensive load calibration tests to determine system sensitivity and repeatability. Various neck inclinations, anteversion and retroversion positions and rotational orientations (about the neck axis) will be tested at low and high load levels to set the gain levels for the six strain channels. The threaded equator of the ball will allow access to the telemetry module and facilitate these adjustments. Once calibrated, these units will be available for on-site demonstrations and for test trials with the data recovery system.

#### STATIC TESTING IN AIR (2 UNITS)

Two prototype units will be externally strain-gauged on the lateral stem and superior neck for static loading tests. These units will also contain a pair of semiconductor strain gauges on the inner neck, will be welded and sealed but will not contain telemetry components. The internal gauges will be powered by hard wire connections at the feedthrough pins located at the stem tip.

One unit will be potted in an acrylic block with rigid distal stem fixation (the 'cantilever mode') and loaded within the elastic range to simulate a 'worst case' loading configuration. The second unit will be cemented into a fresh cadaver femur and loaded similarly. Conditions of cracked acrylic, a loose stem, and a partially fixed stem will be studied with multiple implantations of this prosthesis. New gauging may be required if the existing gauges are damaged upon implant removal. Once a range of loading orientations and fixation modes have been studied for elastic loadings, failure tests will be initiated and the load required to induce plastic strains in the implant will be measured. These will be compared to strain levels calculated from beam theory (neck portion) and to levels measured on commercially available implants in our prior studies<sup>21</sup>, and in other strain gauge studies of a similar nature<sup>1, 24, 31</sup>. Preliminary calculations for our ball-neck configuration shows the anticipated strain levels on the superior neck to be approximately one-half those of the T-28 prosthesis. Experimentally measured strains will enable us to predict the true safety margin of our design over commercially available neck designs.

#### FATIGUE TESTING IN SALINE (5 UNITS)

Five sealed units containing full internal gauging and telemetry will be fatigue tested in a saline-filled chamber. Although these units will contain the gold induction coil at the stem tip, they will be powered by hard wiring through the platinum pins at the glass-metal feedthrough located at the stem tip. The coils will be present to test their mechanical integrity during the 'loose' implantations. These units will be mounted into fresh cadaver femora in a variety of 'best case' implantations (good position with full acrylic support) and 'worst case' placements (varus position with partial acrylic support). A sine wave loading profile will be applied to the femoral head in our MTS 812 servohydraulic test machine and gauge outputs and system performance parameters will be monitored. Typical loading frequencies will be in the range of twenty to thirty cycles per second with some testing at low rates (10 to 20 cycles per second). The testing frequency (and hence the test duration) will be influenced by the biological degradation of the fresh cadaver specimen. Longer tests at lower frequency with implants mounted in acrylic only will be run if specimen deterioration

should not become a problem. Loading orientations will range from 15-25 degrees inclination to the femoral shaft (expected load direction) to a worst case loading with the load parallel to the femoral shaft. Load rates, force levels and orientations, fixation configurations and test durations will be modified during the course of the testing program. It is anticipated that most tests will be in the force range of 500-1000 lbs and be terminated at 20 million cycles of testing.

#### SECONDARY SEAL TESTS IN SALINE (2 UNITS)

Our unit will have two barriers to leakage. The primary seal will be the two electron-beam welds at the ball and stem feedthrough. The secondary seals will consist of a moistureproof coating over the exposed soldered connections, resistors, capacitors, and ferrite toroid. A number of coatings are available for this purpose, including silicone sealers, RTV, solithane and polyimid. The hole in the center of the stem (which will not weaken it substantially, since it is near the neutral axis for bending) will be back-filled from the bottom up with sealer and all exposed components coated. The final selection of sealer will be made on the basis of its biocompatibility performance. Two units will be tested for the effects of leakage of the primary seal (weld sites) and secondary seals. One prosthesis will be immersed in a saline-filled chamber and loaded cyclically. The ball of this unit will not be welded. The saline will be sampled at periodic intervals and a chemical analysis of the amounts and composition of the leached solutes will be measured. This will represent a 'worst case' leakage situation (primary seal breakdown) and will give a baseline for future comparisons. A second unit will be fatigue-loaded in a cantilever mode to produce a crack in the stem tip near the coil. The leakage of solutes up through the sealer-filled hole in the stem (secondary seal) will be similarly measured. This mode will be more representative of an in vivo failure configuration. Chemical analysis of the fluids and the concentration levels will be evaluated with respect to potential human toxic effects.

#### TASK DIVISIONS

The prototype prostheses will be designed and fabricated at UCLA. The strain-gauging, wiring and calibration-testing will be performed at JPL. The structural testing (static and fatigue) will be carried out at UCLA. Secondary seal tests will be a joint JPL-UCLA effort with mechanical tests performed at UCLA and chemical analysis at JPL.

#### 3. Power Induction System

The power induction system will provide the means for powering the prosthesis internal electronics for a number of laboratory tests as well as for the implanted units. Two configurations of the external power induction unit will be provided for this effort. They are described as 1) a bench-test unit for powering non-implantable test units, consisting of an external induction coil and oscillator powered by a bench supply, and 2) a clinical power-induction unit consisting of a waist-mounted oscillator/battery pack with the external coil assembled in a thigh-mounted cuff, all of which are housed in a one-piece assembly made from a suitable fabric. The complete system includes a secondary gold coil wound on the stem of the prosthesis. In order to improve system power-transfer efficiency which would reduce battery power and weight, some redesign work will be necessary in the stem coil design. The present gold over stainless steel configuration results in lower than desired efficiency due to a shorted turn being presented by the stainless steel. Investigation of coil-efficiency improvement

techniques will include: 1) displacing the coil from the stem with a thin dielectric or ferrite (if biocompatible), and 2) placing the coil below the stem supported by suitable non-metallic material. For each investigation, power-transfer efficiency will be maximized by optimizing coil-size, diameter and turn-ratio. Once the electrical performance of the coil configuration is satisfactory, a suitable mechanical configuration for supporting and protecting the coil will be designed. This protective cap will most likely be teflon or polyethylene, and will be mechanically secured to the stem via a mechanical interlock. System electrical tests of the power-induction system will include: power-transfer as a function of vertical placement between oscillator and secondary coils, power-transfer efficiency and oscillator power and frequency stabilities.

#### TASK DIVISIONS

The power-induction system design and performance testing will be carried out at JPL. The induction pickup coil design will be a combined JPL-UCLA effort, as both electrical performance and mechanical interfacing with the stem tip are involved.

#### 4. Hermeticity

Sealing tests will be performed on the welded prosthesis to measure the degree of hermeticity of the weld joints. The hermeticity test is performed by placing the prosthesis in a chamber pressurized with helium at 60 psig for 15 hours to force the tracer gas into the prosthesis via any leak paths, after which gross and fine leak-tests are performed in a helium mass-spectrometer. Immediately after bombing, the prosthesis is placed in the vacuum chamber of the helium mass-spectrometer and the chamber is evacuated.

There are two tests performed to complete the hermeticity check: gross leak and fine leak. The gross leak-test is performed while the vacuum chamber is being evacuated, which will sense any large leaks. The fine leak-test is then performed at  $1 \times 10^6$  torr. If a leak were to exist, it would have shown at this stage as a helium flow from the prosthesis into the vacuum chamber, and a detector tube would indicate the helium flow as a leakage rate.

A second gross leak test, called a wet test, is also performed by first bombing the unit in a pressure chamber containing freon liquid for 4 hours and then submerging the prosthesis in 100 degrees C fluoroinert detector fluid for 60 seconds. A leak will be indicated by the presence of a stream of small bubbles rising from the prosthesis.

These leak-tests will be performed on every unit after welding and polishing of the femoral ball. Hermeticity will also be checked during various stages of the mechanical testing program and upon completion of all tests. If leaks should be detected at any stage, the prosthesis will be sectioned at the defect and a metallographic analysis performed to pinpoint the problem.

#### TASK DIVISIONS

All tests for hermeticity and leakage will be performed at JPL.

## 5. Component Biocompatibility

Two aspects of prosthesis biocompatibility will be studied. One region of interest is the final coil configuration at the stem tip. The coil, with protective plastic cap, will be encased in acrylic bone cement and implanted in the back musculature of a dog. Routine histology will be performed on the tissues surrounding the implant site to evaluate the soft tissue cellular response. A second concurrent study will determine the effectiveness of the secondary seals (the coating of the electrical components). Trial implant units will be prepared, consisting of a portion of the mother board containing a submodule, soldered pin-connections, ferrite toroid, a resistor and a capacitor. All components and electrical connections will be coated with RTV (or equivalent) and placed in the back musculature of a dog. At sacrifice, aspirated fluids and tissue samples will be chemically analyzed for the presence of trace-elements and their concentrations, in addition to histological analysis. The sealant exhibiting the best performance will be selected as the final choice for the eventual human implantations.

Multiple implant specimens are planned for each experimental animal. Because of the physical size of the components, dogs have been selected for this purpose. One-, three-, and eighteen-month sacrifice schedules are planned with two dogs in each category.

## TASK DIVISIONS

All animal implantations and subsequent tissue analyses will be done at UCLA. Specimen preparations for animal studies will come from both JPL (sealed telemetry components) and UCLA (external coil configuration).

## 6. Data Recovery and Display

The complete broadcast datastream will be recovered in real time with an FM receiver (block diagram shown in Fig. 1). The FM datastream will be decoded and the resultant analog datastream will be simultaneously recorded on FM tape, displayed on an oscilloscope, and shunted into an A/D converter situated at the front end of the display system. The real-time display of each channel will indicate the state of each strain gauge, assuring early detection of any erratic gauge behavior.

The data will be analyzed using the Microprocessor-Enhanced Display System (MEDS) currently under development at the Biomechanics Research Section, Division of Orthopedic Surgery, UCLA. MEDS consists of a closed-circuit color television subsystem, a 64-color digital display subsystem, and the hard- and software required to interface these subsystems to the controlling minicomputer. The MEDS hardware was underwritten entirely by donations received through the efforts of patients who have received total-joint replacements at UCLA.

MEDS functions as described below:

Software will be written which will enable a programmable clock to specify sampling windows in the telemetered analog input datastream. These sampled data will be converted to a digital datastream by the A/D converter and transformed into a series of 3-space digital vectors, and written directly onto disk. The software required for this task will be written in single precision Fortran IV. Using data from six of the ten sequential channels, the program will compute forces in three orthogonal directions, along with the magnitude and direction of resultant force vectors. The program will also yield a running average and standard deviation of resultant force-vector

magnitudes. Using these statistics, vectors with magnitudes greater than pre-selected values from the average will be automatically detected and printed. Thus, whether the data are generated by an engineering model mounted on the MTS machine or by a prosthesis implanted in a patient, it will be possible to obtain immediate graphical feedback regarding both the average magnitude and the frequency of larger magnitude-vectors, and, because the display system is color-programmable, it will be possible to display vectors of certain large magnitudes in brighter colors, for example, relative to those nearer the average.

Verification of software calculations will be accomplished by mounting engineering models on the MTS machine. This procedure will allow loads of known magnitude and orientation to be applied to the models, and software modifications (if necessary) resulting from such trials will assure accuracy over a wide range of values.

A Fortran-callable graphics subroutine will be written which will display these results as foreground vectors graphically 'blinked' onto a color receiver/monitor at a software-selectable rate. This will be accomplished using a medium-resolution digital display-system controlled by a programmable graphics processor. The 'blinking' vectors will be concurrently interlaced with one of several background datastreams. The background menu will eventually include digitized x-rays of prostheses in vivo, rotatable finite-element models of prostheses, and videotapes of engineering models in vitro or other subject behavior recorded at the time of the telemetered event. When the background selected is a subject or patient activity, movement will be detected by a studio color camera and recorded on VHS videocassettes. Mixing of videotapes with other composite video sources such as x-y plots and labeling information will be possible using a special-effects generator. The fully-mixed image series will then be displayed on a color TV monitor and/or recorded in parallel, and/or digitized, buffered, and written to disk.

The minimum data-base for each subject activity or patient visit will thus consist of a) movement-specific vector sets written directly onto disk; b) buffered video frames selectively written to disk, and c) video cassettes containing historical datastreams in variable split-screen and interlace modes.

MEDS is a unique juxtaposition of subsystems, each of which was initially engineered to stand alone. The successful marriage of the components of these subsystems will be facilitated by consultation with audio-visual, mainframe, auxiliary- and graphics-software specialists. Several individuals have offered their expertise in exchange for the opportunity to be associated with MEDS.

Statistical analyses will make feasible the testing of a series of hypotheses regarding movement and force. These are expected to range from an initial examination of correlations to eventual tests of specific hypotheses exploring possible relationships of movement, force, prosthesis design, and subject or patient outcome. Statistical tools utilized will include software written for the minicomputer, as well as batch submissions to the UCLA IBM 370/3033, thereby accessing the BMDP, SPSS and SAS statistical packages. Utilization of the IBM 370/3033 is expected to occur when statistics are required of a very large data-base, or when specific algorithms are desired but are not available on the minicomputer.

Using MEDS, results of such tests will be easily displayed and communicated to other researchers and clinicians. Consider as one example the possibility of mapping the intersection of a series of vectors onto the 35-millimeter spherical surface of a modelled prosthetic total hip. As a controlled subject or patient activity occurs, the sequential change in orientation of the resultant force-vectors would be mapped pixel by pixel on the surface of the model, while vector amplitudes would be represented

by corresponding changes in pixel hue, with warmer colors representing greater amplitudes. Thus, activity-specific schematics with normal displacement and amplitude changes could be recorded, and incremental deviations from normal distributions would have useful prognostic value.

MEDS extends the traditional range of clinical evaluation tools. MEDS allows the clinician to visualize force and motion quantitatively, and to actively integrate these vector data with corresponding patient activities. Over a period of several patient visits the clinician will be able to objectively assess progress both among visits and between patients. MEDS will thus serve as a robust clinical tool, providing both immediate feedback and objective longitudinal evaluation.

#### TASK DIVISIONS

The data acquisition and printout system will be developed at JPL. Computer calculation of vector components, graphical displays, and associated software for statistical processing of the information will be carried out at UCLA.

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## E. FACILITIES AVAILABLE

### UCLA Biomechanics Research Section

1. Materials test facility, including an MTS 812 servohydraulic test machine with associated function generator, oscilloscope and x-y recorder.
2. Research and development machine shop.
3. Instrumentation lab.
4. Minicomputer with color video and digital graphic display subsystem (projected installation August 1980).

### UCLA Center for Health Sciences

1. Soft tissue histology laboratory with capabilities for transmitted light, reflected-light and SEM microscopy.
2. Capabilities for paraffin-embedded and plastic-embedded soft tissue specimens plus calcified and decalcified bone tissue.
3. An animal surgical facility with fourteen operating rooms with full veterinary supervision of operative and post-operative animals.
4. A complete animal x-ray facility.

### Jet Propulsion Laboratory

#### 1. Dynamic Environmental Test Facility

##### a. Vibration equipment

The Dynamic Test Group has vibration test equipment capable of testing complete spacecraft as well as small components. There are twenty-two electro-dynamic exciters and one electro-hydraulic exciter in this facility. This system is capable of sinusoidal, random and shock control.

##### b. Mechanical load testing

The mechanical test facility at present utilizes an MTS servohydraulic which can accurately measure materials responses over load ranges required for testing of the prostheses. Test speeds are widely variable as are the types of loading. Data acquisition is via x-y plotters and storage oscilloscopes.

#### 2. Fabrication Services

##### a. Fabrication services

The fabrication services section within the Facilities and Fabrication Services Division is responsible for providing a wide variety of fabrication services to all elements of the Laboratory. The section is comprised of machine shops, a sheet metal shop, a welding shop, technician fabrication work areas, and will provide fabrication engineering and fabrication liaison. The fabrication services section provides a modern fabrication facility which has pioneered many significant advances in aerospace fabrication technology.

b. Special projects shop

All aspects of custom apparatus fabrication are provided in this shop: prototypes, developmental models, R&D work, flight-type mechanisms and parts. Sketches and other records can be produced as the job progresses so that the final design is more easily documented.

c. Plastics lab

This lab offers plastics application services for both flight and non-flight needs. These services include encapsulation of modules, impregnation and encapsulation of transformers, bonding of boards, components and conformal coating of printed circuit boards. The requestor may work directly with the plastics technicians in development work or furnish complete documentation for a flight-certified job.

3. Spacecraft Radio Hybrid Microelectronics Laboratory

The Spacecraft Radio Section, Hybrid Microelectronics Laboratory is as a clean room facility for the fabrication of microminiature hybrid radio assemblies. The room, with its horizontal laminar air flow, is divided into two sections. The first room is used for photolithographic substrate patterning and microscopic inspection, while the second room is used for component storage and assembly processes. Discrete electronic parts including integrated circuits are assembled into ceramic submodules using a combination of space-qualified techniques. The submodules along with the larger discrete and adjustable parts are then assembled via batch reflow soldering into module assemblies which represent a functional block, such as a biotelemetry assembly.

4. Mechanical Instrumentation Facility

This lab has complete facilities for mounting and wiring foil and semiconductor strain gauges. The group supports pre-flight testing of mechanical mock-ups of space-flight systems and some in-flight hardware.

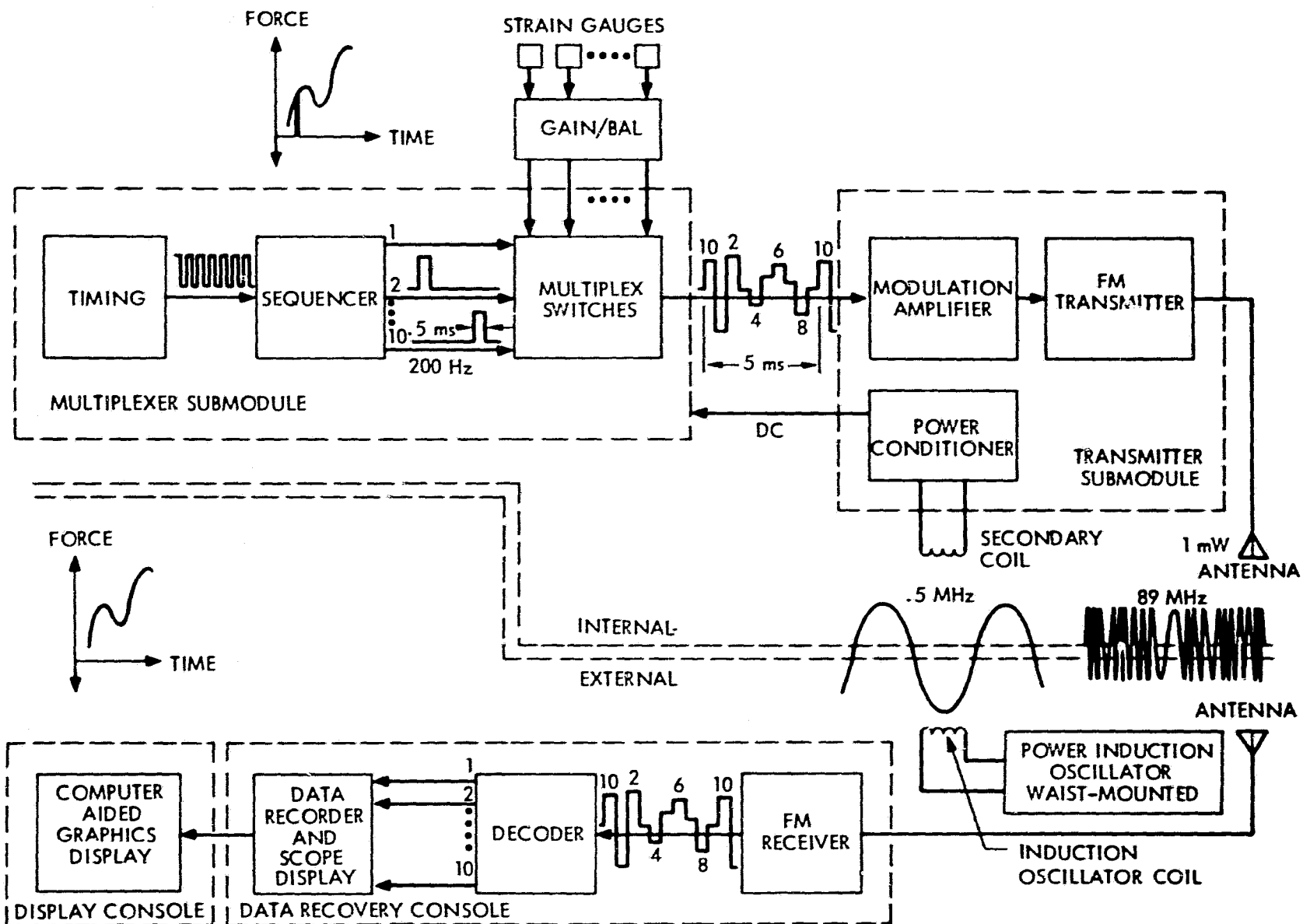
5. Leak Test Facility

This lab has equipment for measuring the degree of hermeticity of sealed component parts, submodules and complete electro-mechanical assemblies. The facility provides capability of both gross and fine leak measurements through helium mass spectography.

The undersigned agrees to accept responsibility for the scientific and technical conduct of the research project and for provision of required progress reports if a grant is awarded as the result of this application.

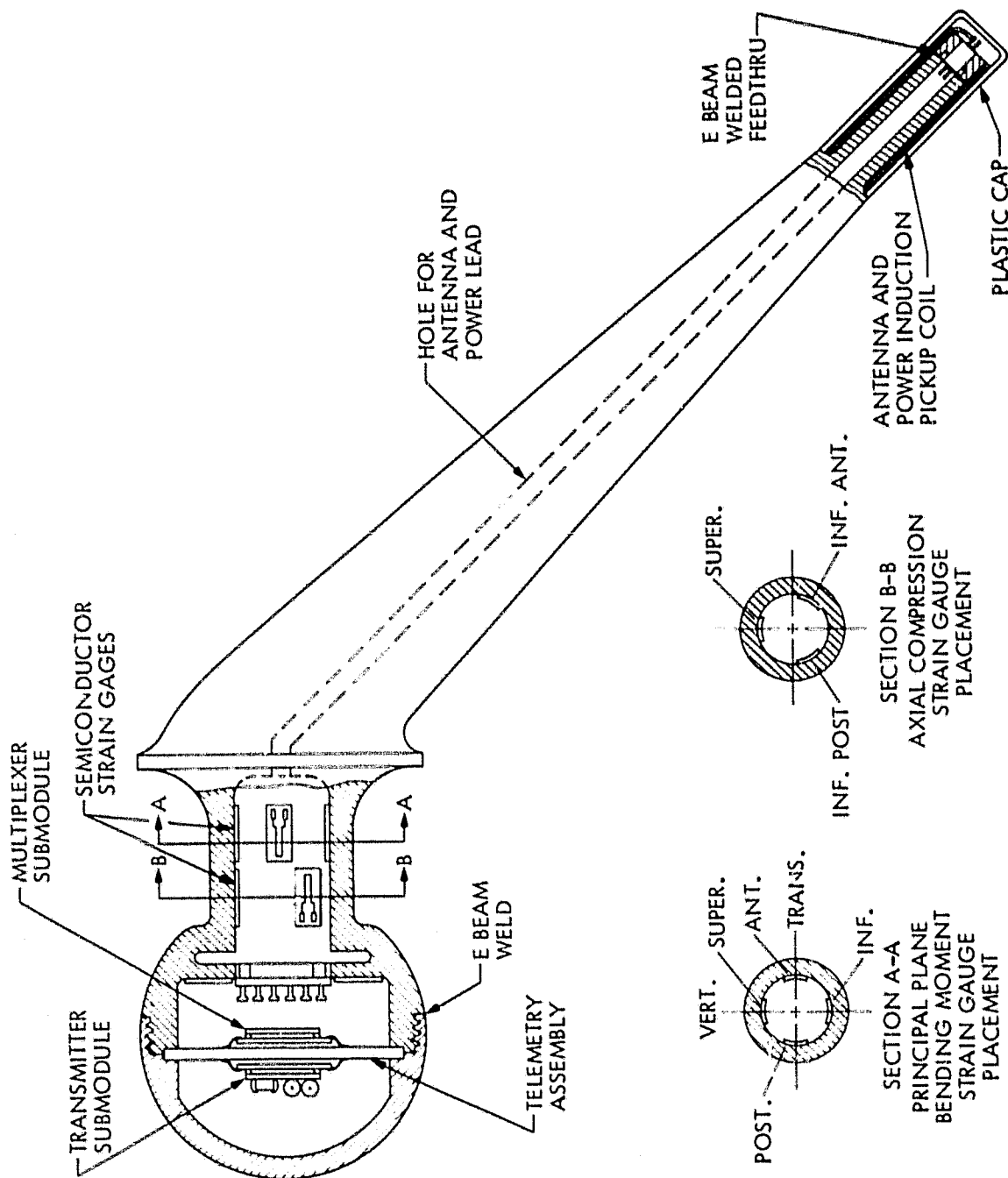
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Date

Keith Markolf  
Principal Investigator



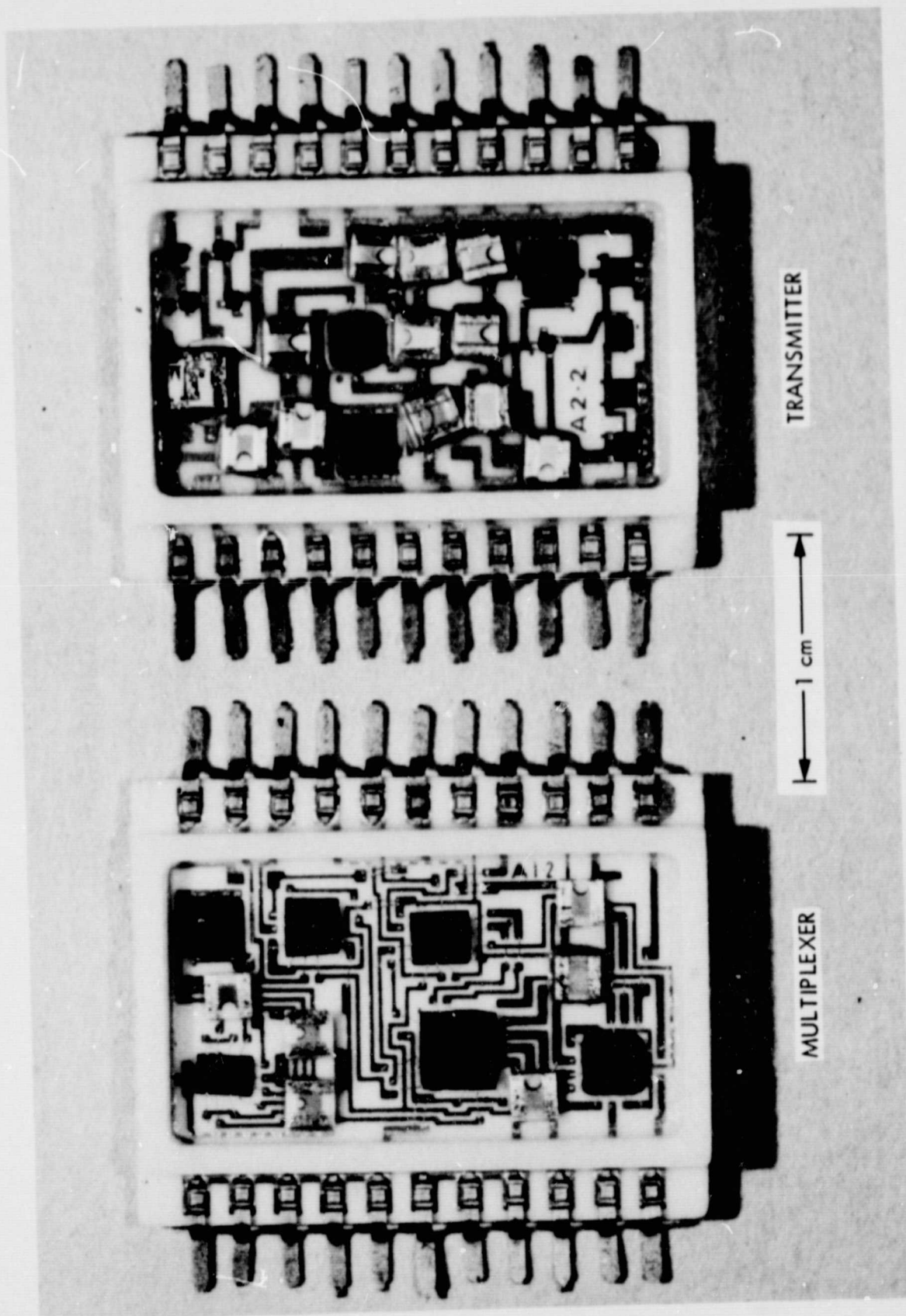
BIOTELEMETRY BLOCK DIAGRAM

FIGURE 1



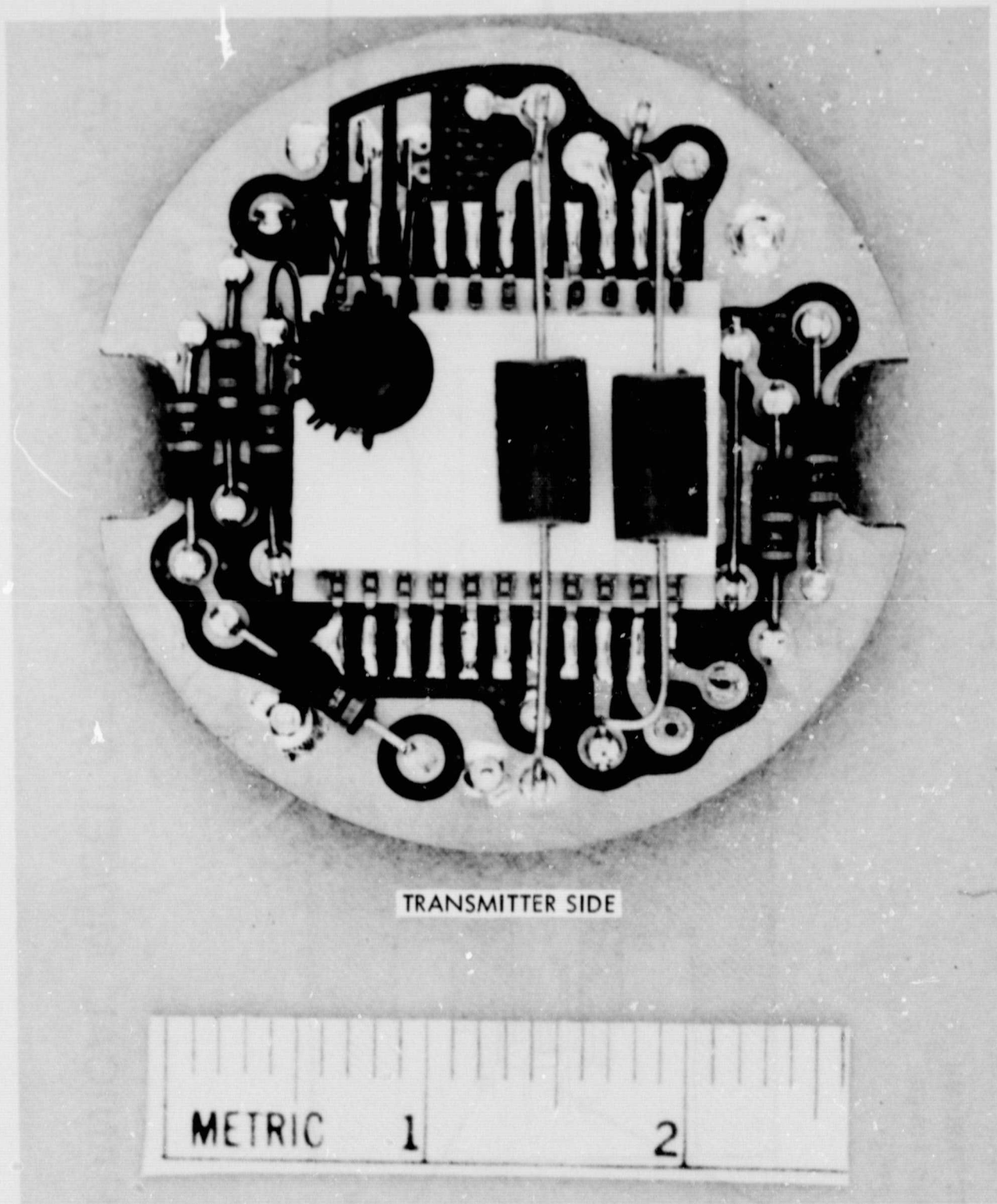
INSTRUMENTED PROSTHESIS DIAGRAM

FIGURE 2



UNSEALED TELEMETRY SUBMODULES

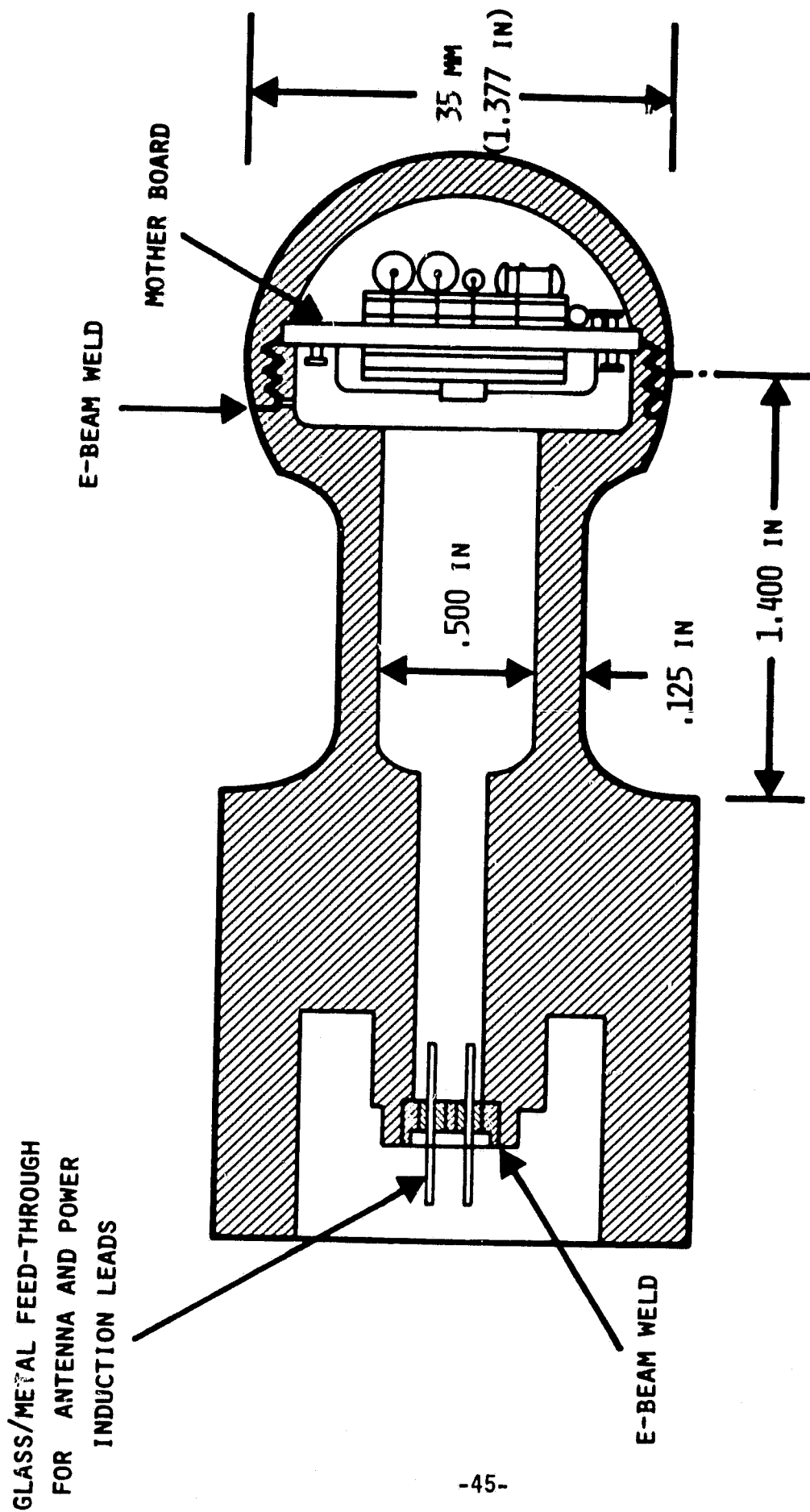
FIGURE 3



TELEMETRY ASSEMBLY

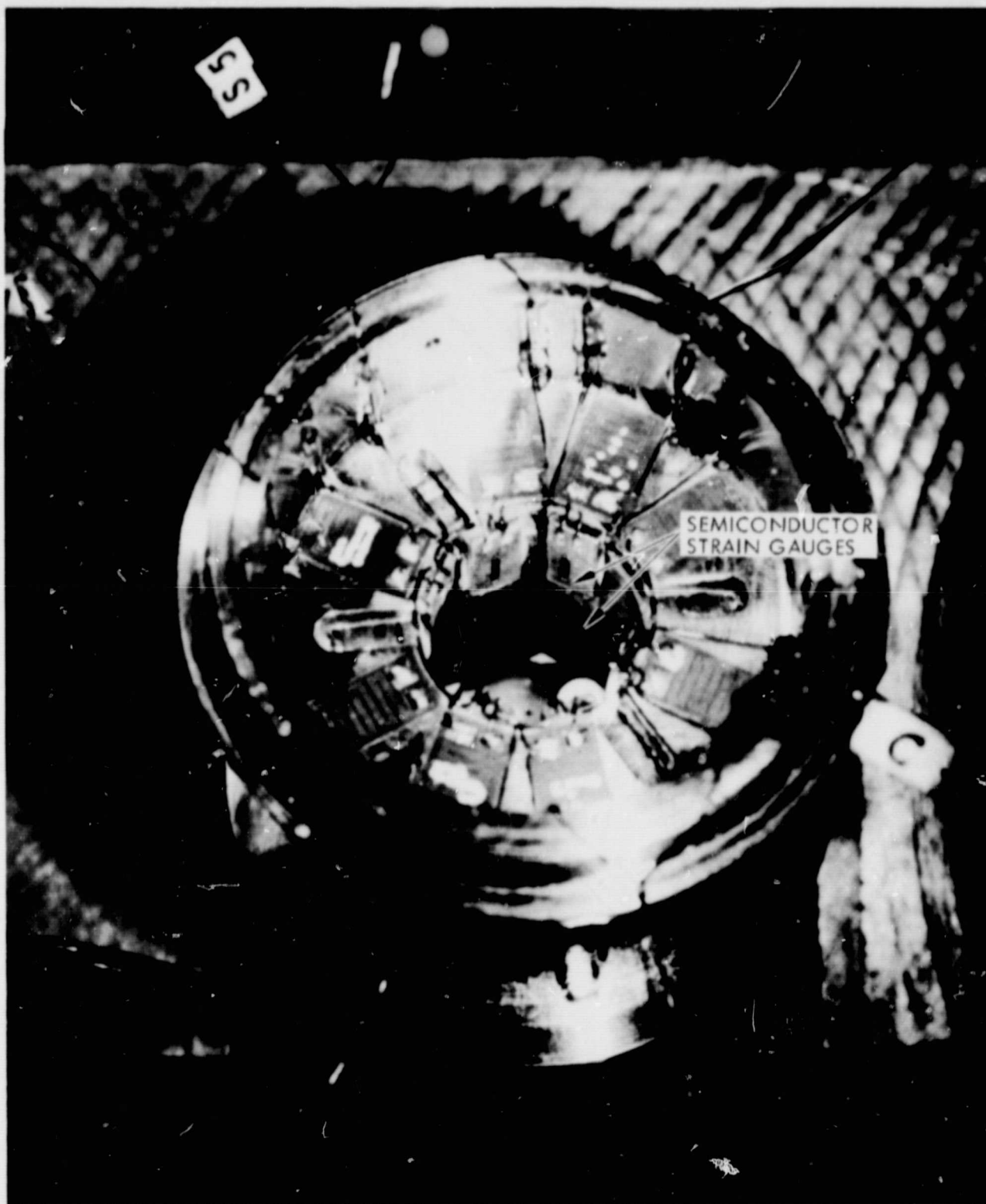
FIGURE 4





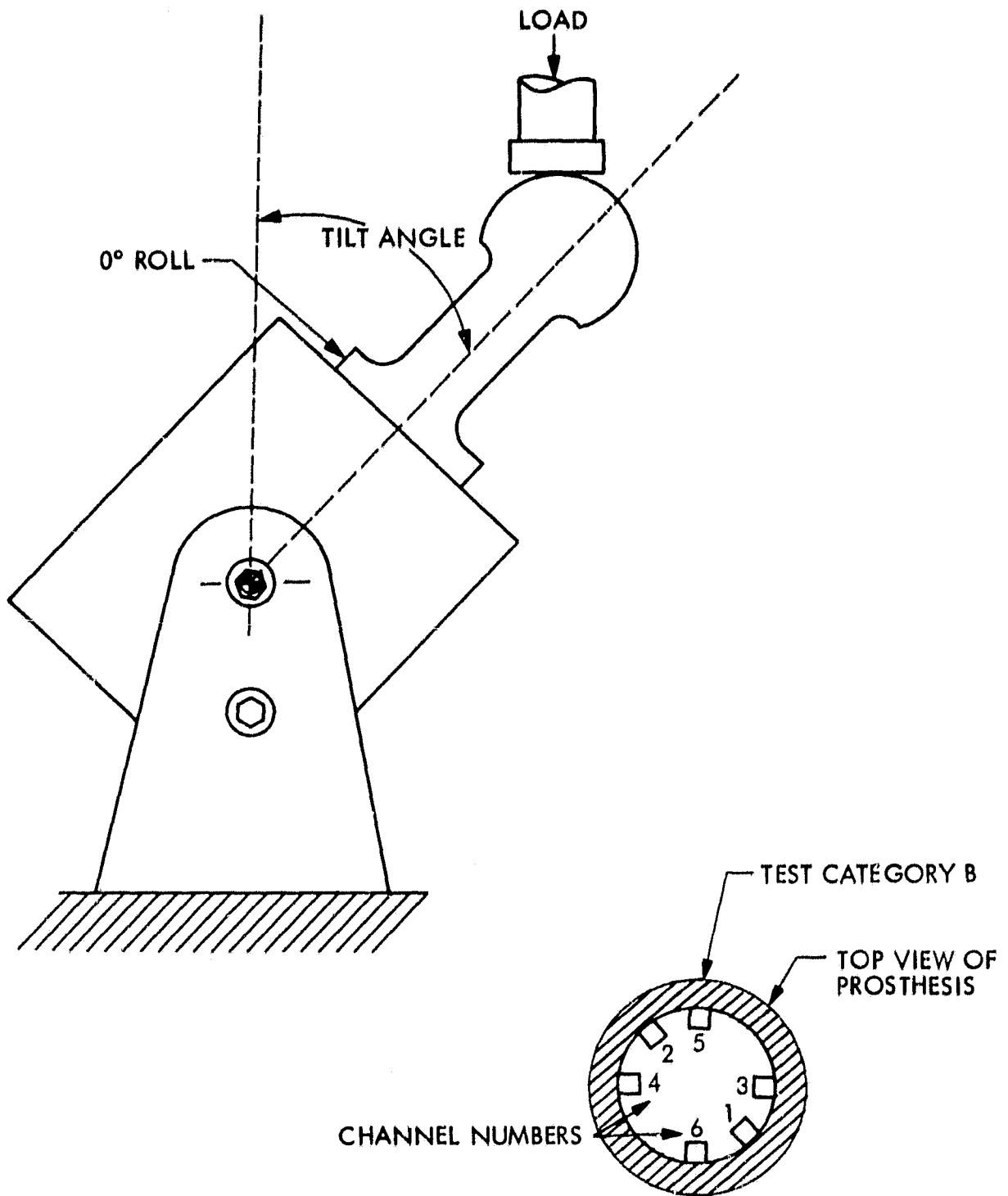
MECHANICAL MODEL OF PROSTHESIS BALL AND NECK

FIGURE 5



PROSTHESIS INTERNAL NECK VIEW  
FIGURE 6

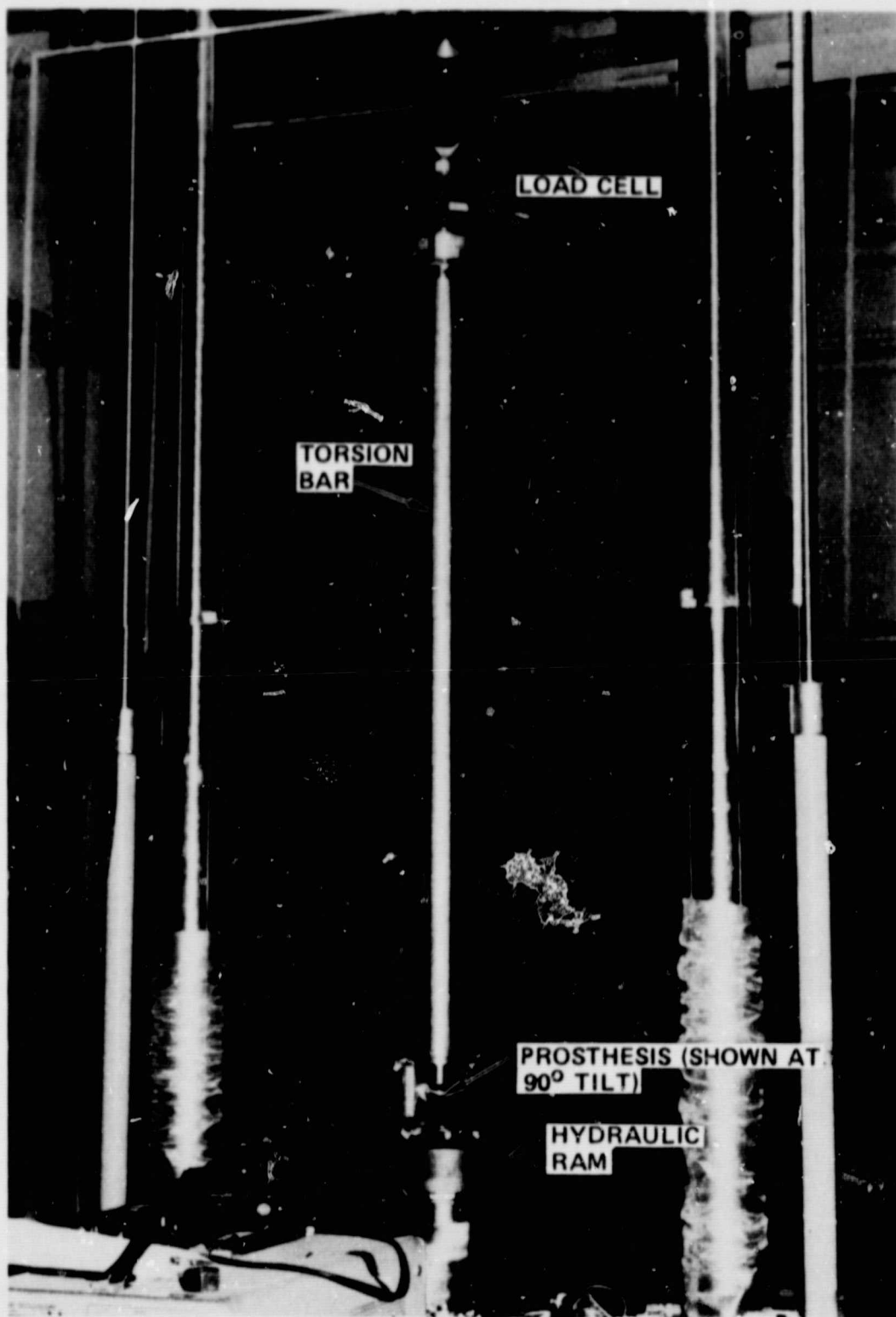
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STRAIN GAGE PLACEMENT

STATIC TEST FIXTURE CONFIGURATION

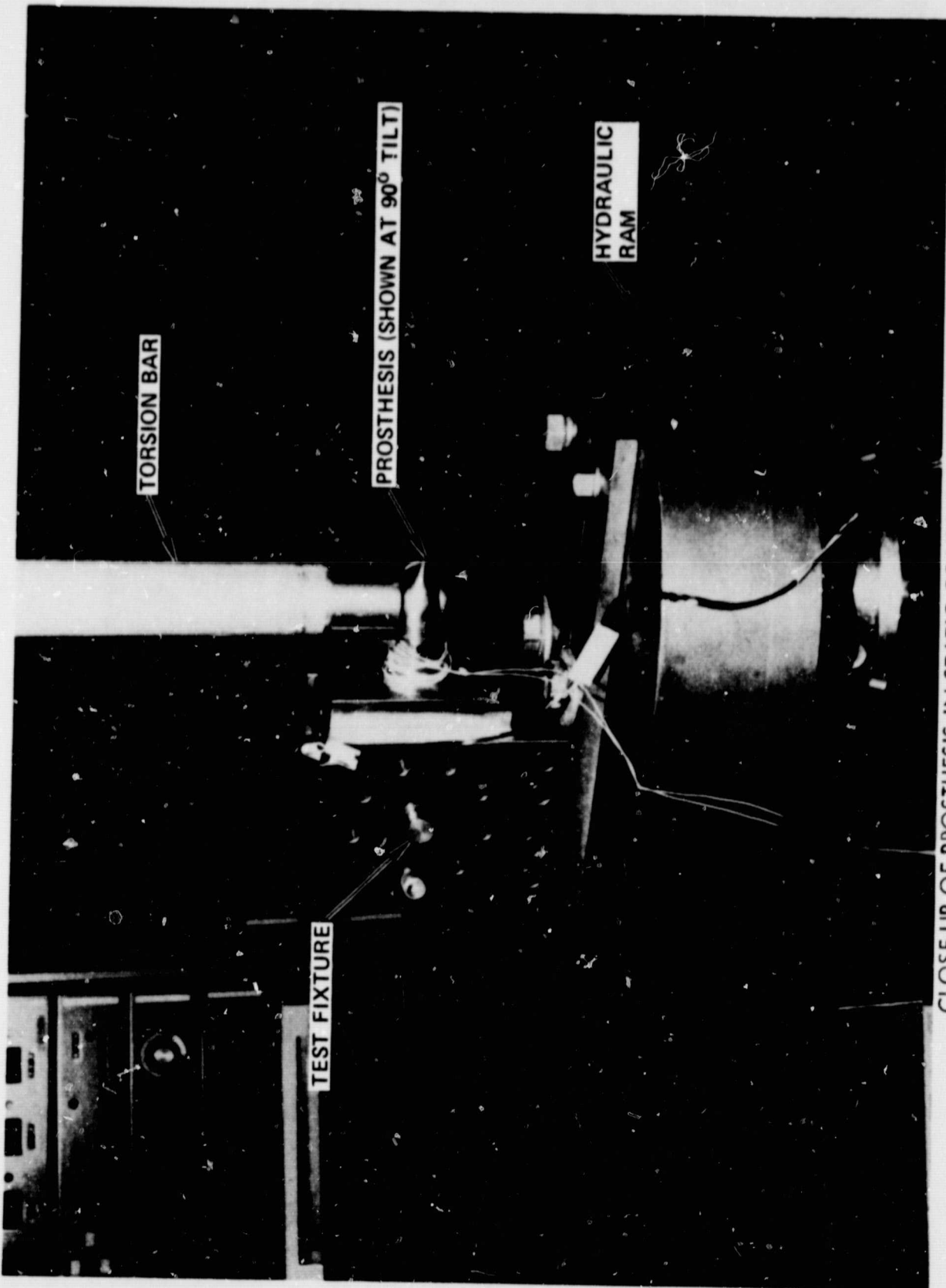
FIGURE 7



PROSTHESIS MOUNTED IN MTS SERVO HYDRAULIC  
PRESS FOR STATIC LOAD TESTS

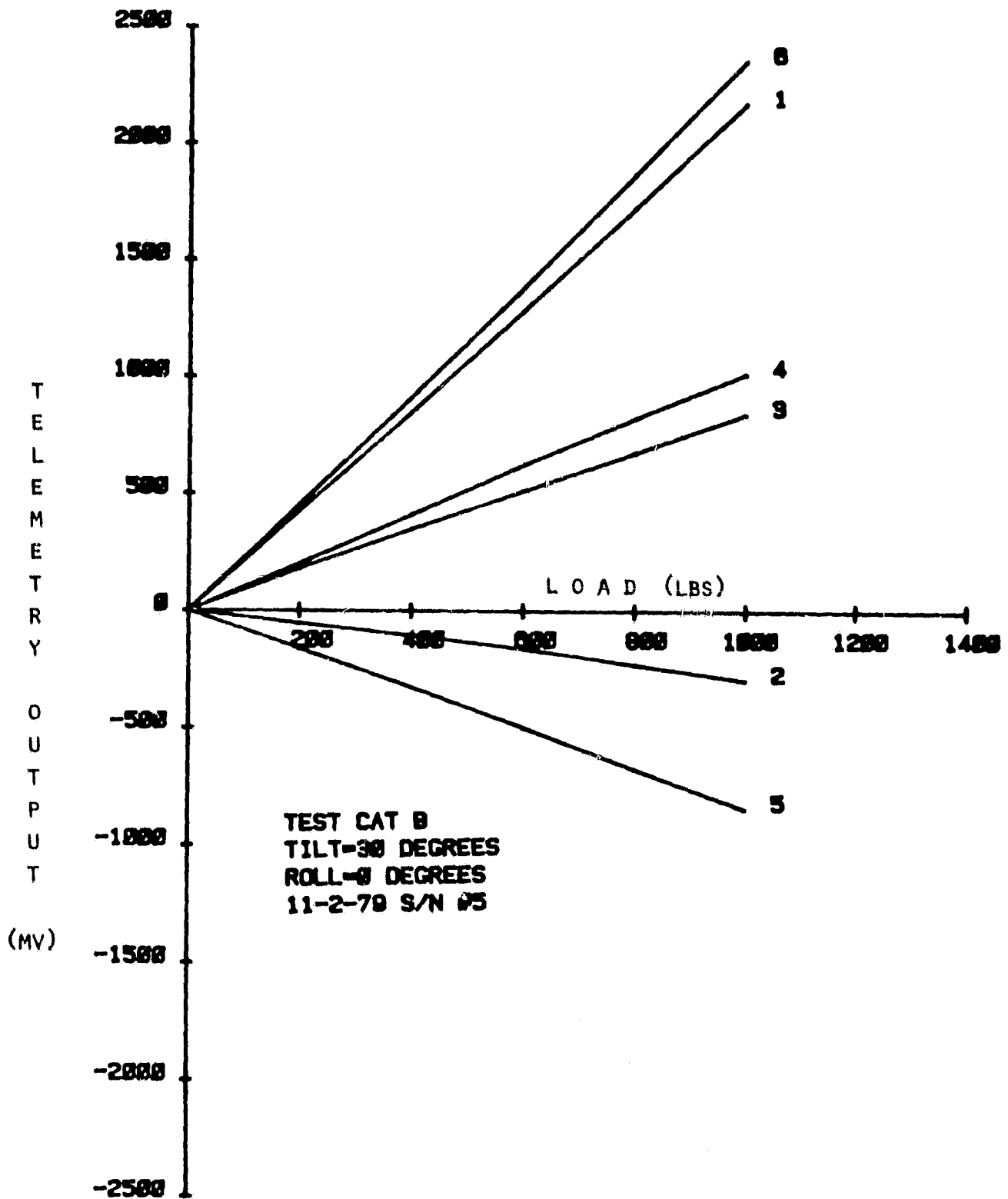
FIGURE 8

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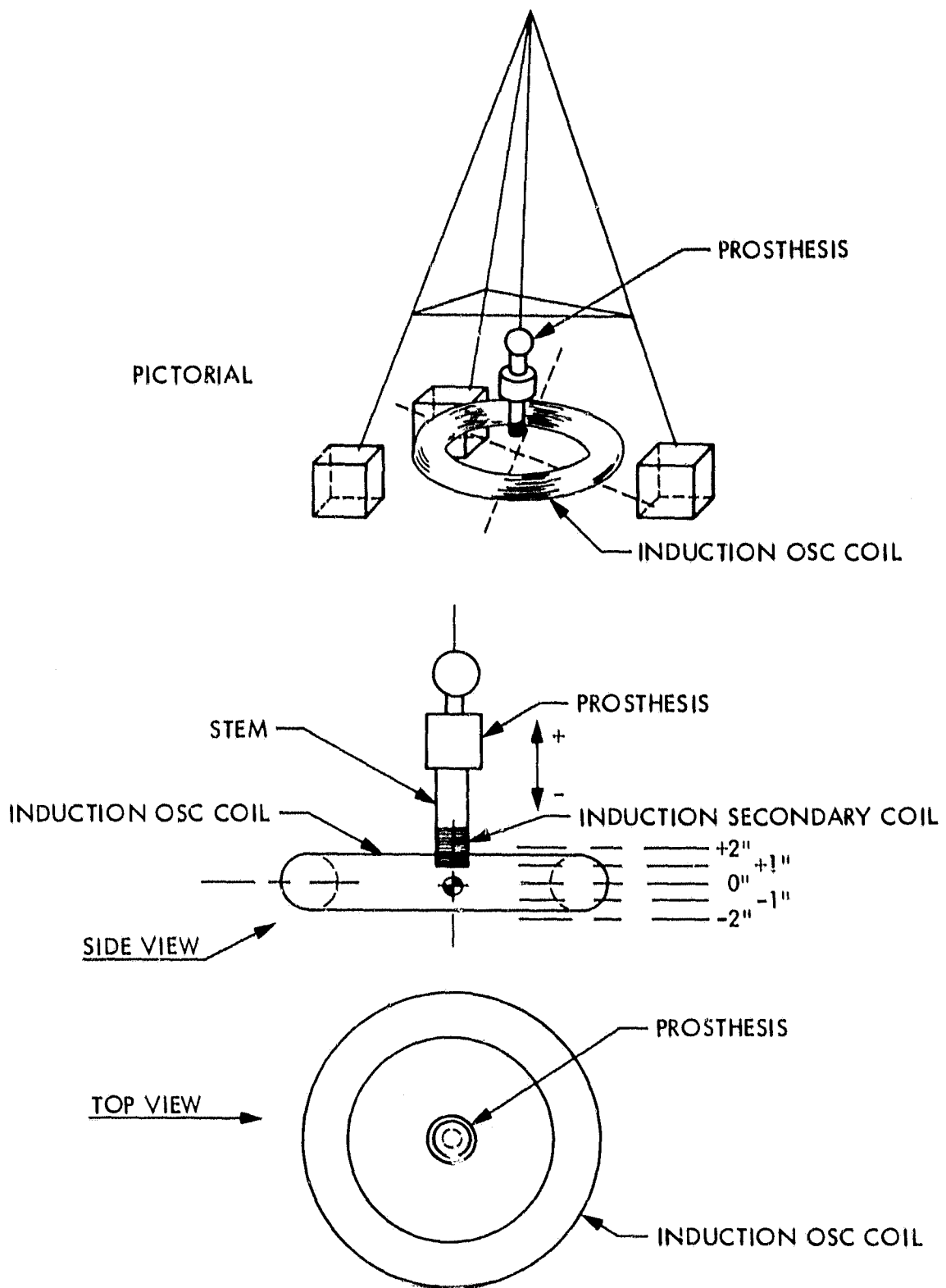
CLOSE UP OF PROSTHESIS IN STATIC COMPRESSION TESTER

FIGURE 9



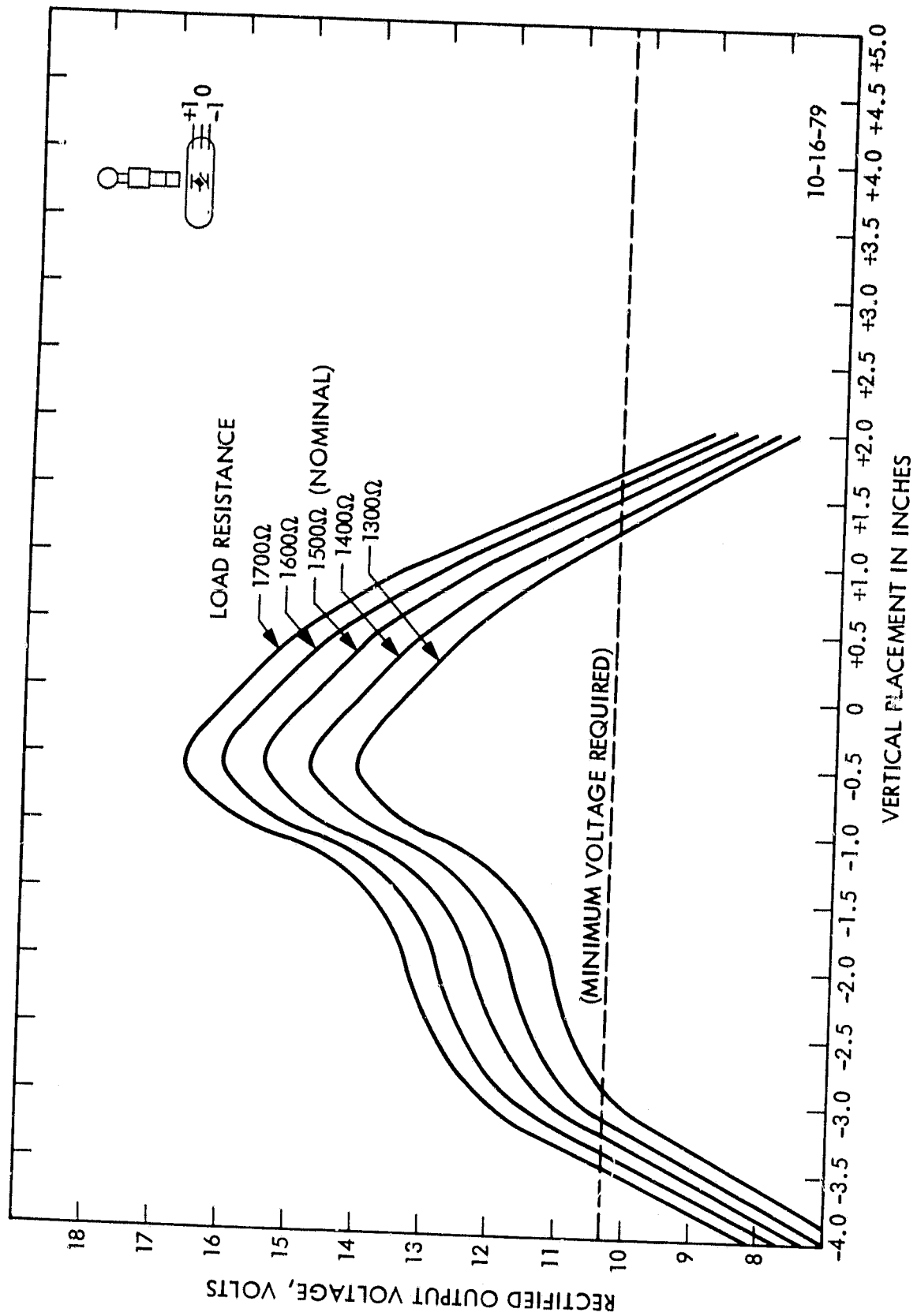
COMPUTER PLOT OF TYPICAL TELEMETRY OUTPUT

FIGURE 10



POWER INDUCTION VERTICAL PLACEMENT SENSITIVITY TEST

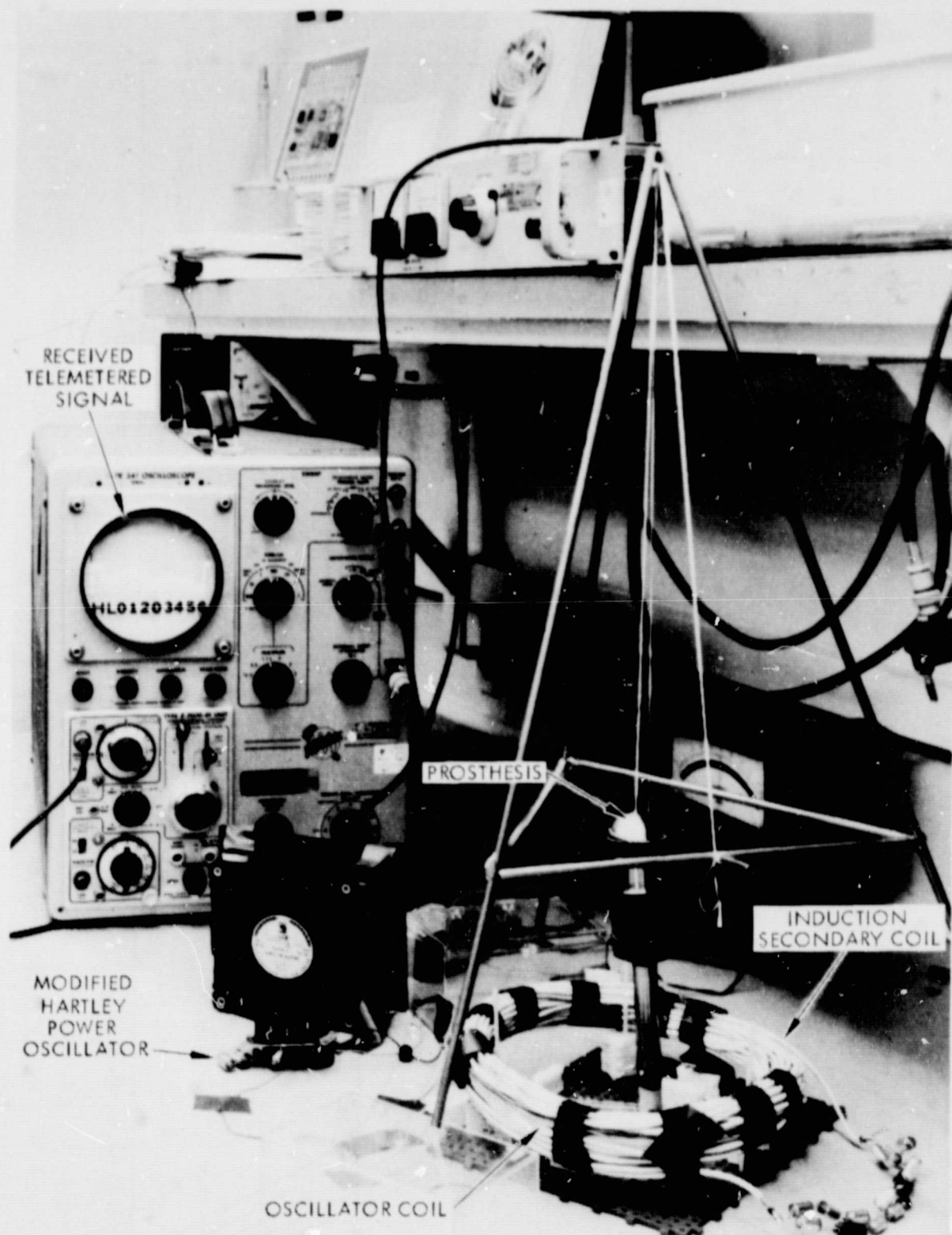
FIGURE 11



INDUCTION SYSTEM POWER TRANSFER vs COIL DISPLACEMENT

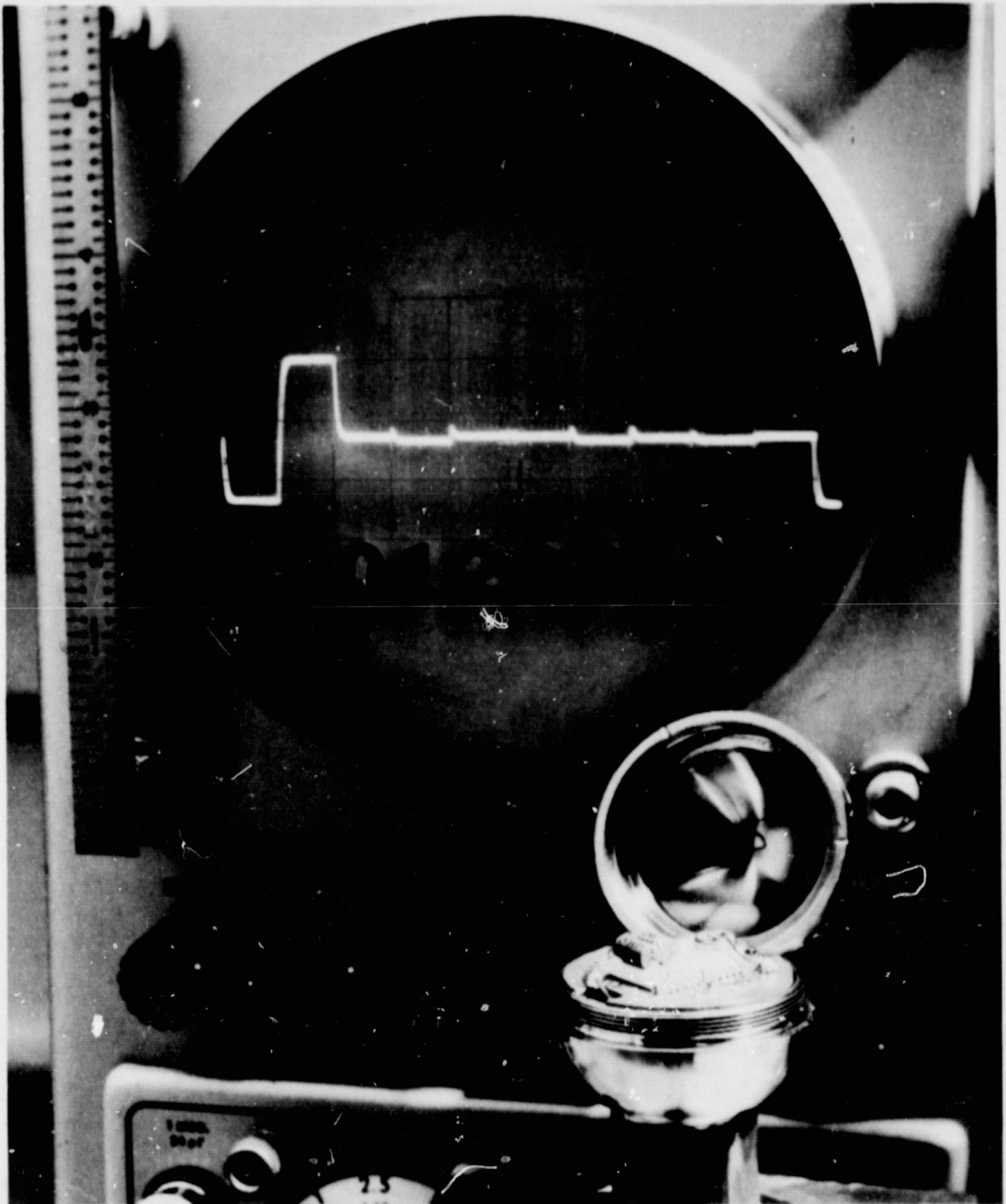
FIGURE 12





OPERATIONAL PROTHESIS WITH COMPLETE POWER INDUCTION SYSTEM

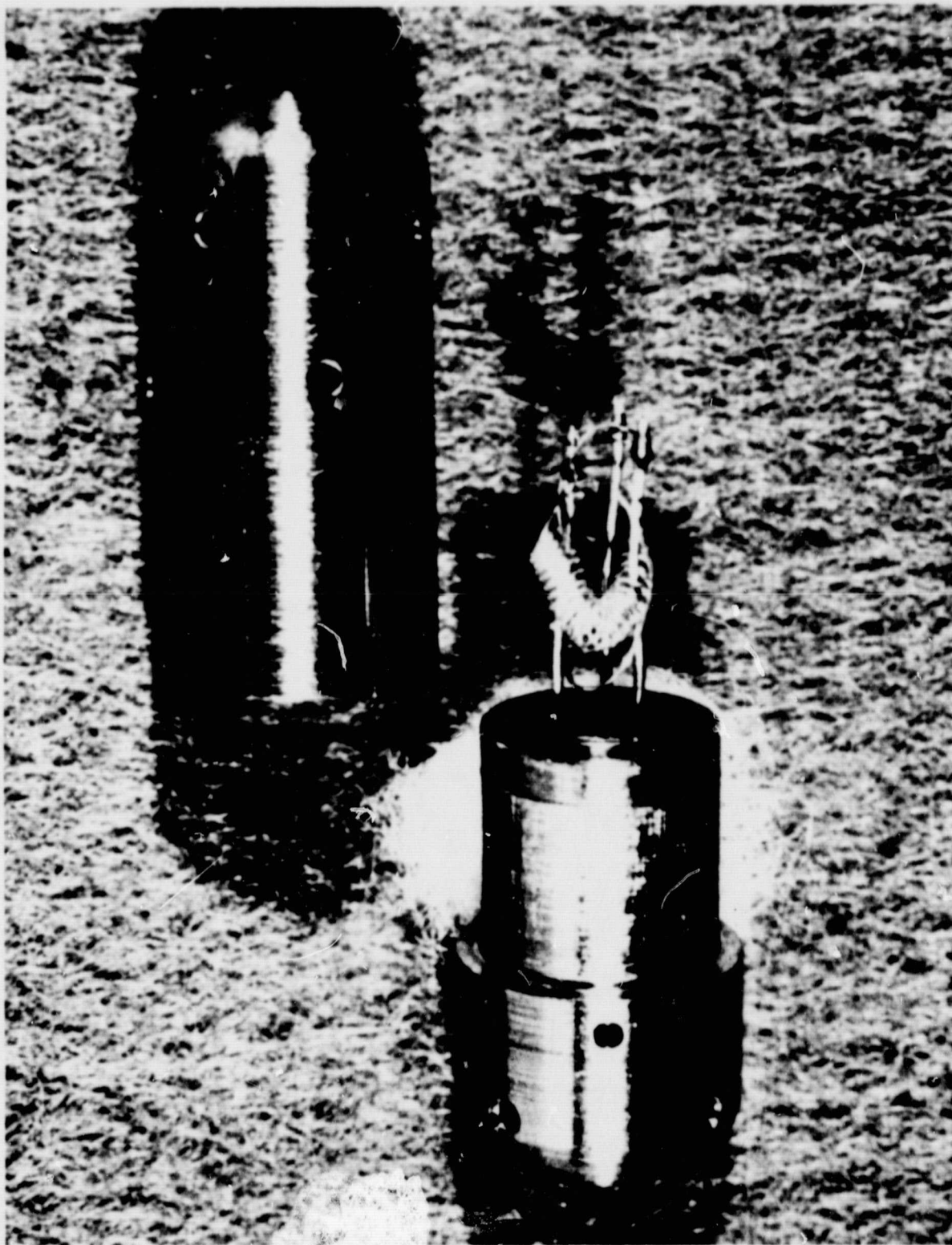
FIGURE 13



PRESEALED PROSTHESIS WITH TYPICAL TELEMETERED OUTPUT

FIGURE 14

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STAINLESS STEEL FEED THROUGH WITH GOLD COIL  
MOUNTED IN CAPSULE FOR DOG IMPLANTATION  
FIGURE 15



A FEMUR IN A SALINE-FILLED CHAMBER  
MOUNTED IN THE MTS FOR FATIGUE TESTING

FIGURE 16

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APPENDIX C

UCLA LETTER SUPPLEMENT TO NIH DATED AUGUST 12, 1980

NIH LETTER DATED JULY 15, 1980



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SANTA BARBARA • SANTA CRUZ

DIVISION OF ORTHOPEDIC SURGERY  
BIOMECHANICS RESEARCH SECTION  
REHABILITATION CENTER  
1000 VETERAN AVENUE  
LOS ANGELES, CALIFORNIA 90024

August 12, 1980

Ileen Stewart  
Executive Secretary  
Applied Physiology and Orthopaedics Study Section  
Division of Research Grants  
National Institutes of Health  
Bethesda, Maryland 20205

Dear Ileen:

Thank you for your letter of July 15, 1980, requesting additional information concerning our grant application AM 27836-01 entitled Total Hip Implant - Biotelemetry. This letter is written in response to the questions raised by the Study Section. In the five months since submission of our proposal, progress has been made on our system, and we have additional information concerning a prototype design and power induction system. I believe this new material will help to answer some of the questions of the study section. Enclosed are seven preliminary drawings describing a prototype implant configuration and two photographs. Five sets have been provided for the reviewers. This material is itemized in reply. For convenience, I enclose a copy of your original letter in which I have attempted to identify twelve specific items which require a response. We will address them in the order presented.

#### 1. Location of the Induction Pick-Up Coil

There are a number of factors which determine the position of the pick-up coil. First, the coil must be external to the implant since any surrounding metal would prevent power induction. Second, it must be wound around the implant at a location compatible with the position of the external coil worn around the patient's leg--a requirement which argues for distal coil placement. The coil will be isolated electrically from the stem by a thin-walled delrin bobbin (see Detail C - coil assembly). Another thin-walled delrin shield covers the coil, and an end-cap is screwed onto the metal stem tip to protect the feed-through. It is possible that the localized stress distribution near the delrin-cement interface may be altered by the reduced section of the stem tip and the presence of the coil with plastic cap. However, we feel that this effect would be of minimal risk to the patient with our current cement techniques. In the early days of total hip replacement, distal loosening of the stem accompanied by acrylic cracking was a somewhat rare occurrence. Our new cement techniques include plugging of the distal canal, controlled blood ooze at the interface by either hypotensive or epidural anesthesia, thorough irrigation, pulsating lavage under direct fiberoptic light visualization, early insertion of acrylic with containment and pressurization by vigorous finger packing through a rubber sheet which seals the proximal opening in the femur. When

x-rays of patients who have received implants with this technique have been analyzed, distal cement coverage is excellent. In our analysis of current x-rays, distal loosening has not been observed. Since our stem is somewhat longer than current commercial implants (with the exception of certain revision stems), we believe that good cement filling in the canal above the coil tip will insure excellent stem support and effective stress transfer to the cement in this region, diminishing the effect of the relatively "soft" stem tip. We feel that the addition of the distal coil should present a minimal risk to the patient. We intend to verify this by our fatigue test program on implants mounted in cadaver femurs. Both well fixed and distally loose stems will be tested to assure adequate strength. Careful inspection of the stem tip will be performed. Distortion of the stem cap, evidence of acrylic cracking and loss of hermiticity would be indicators of potential problems. In the unlikely event that problems should be encountered, design modifications would be considered.

## 2. Implant Removal Should Revision be Required

The outer diameter of the delrin shield is flush with the blended surface of the stem, presenting no step or notch for cement locking. The end-cap holds the bobbin-shield assembly onto the stem tip. Since the distal-stem contour is smooth with no added bulk, no additional difficulty will be presented should surgical removal be indicated.

## 3. Soft Tissue Radiation Damage

We agree with the reviewer that the radiation damage from the power induction system should offer little risk to the patient. Experience with inductive charging of cardiac pacemaker batteries plus the animal work cited in the proposal leads us to believe the effects should be negligible.

## 4. Effect of the Hole in the Stem for Power and Antenna Leads

The weakening effect of the hole in the stem will be negligible. Since it will be located at the neutral axis of the stem, the .125 inch diameter hole will reduce the moment of inertia .07% in the proximal stem, .28% at the upper margin of the coil location, and 5% at the cylindrical section where the coil is wound. Tensile bending stresses on the outer surface of a well-cemented distal stem have been shown to be minimal by numerous strain gauge studies in the literature. We, therefore, do not foresee a problem from the central hole.

Although the prosthesis is slightly longer than our current version, it is still smaller in size than several current conventional designs, including the Buck-32 and large stem Mueller designs. Even though there is increased length should revision be required, we do not believe that there is any additional risk to the patient using our current revision techniques. We, in fact, have successfully revised 25 mm stem lengths using special high speed burrs and image control without penetrating the femoral cortex.

## 5. Material Choice for the Stem

Only two of the currently available implant materials are machinable. These are Ti 6 Al4Vn and 316 LVM s.s. Both are very tough to work and have advantages and disadvantages. It is true that 316 s.s. T-28 prostheses have

undergone fatigue failures--normally for heavier patients who have had decreased proximal cement support (cantilever fatigue mode). Zimmer USA has indicated that the 1½ inch diameter bar stock used for the T-28 prosthesis has a yield strength of approximately 60,000 psi. A 43° bend is made in the fabrication process to establish the 137° neck-shaft angle. The 316 s.s. which we had considered has a yield of approximately 45,000 psi in the form of a 1½ inch thick flat plate. The implant would be machined totally from this plate with no bending during manufacture. Therefore, no residual stresses, other than those from normal machining and cold-rolling will be present.

The titanium alloy is considerably stronger than 316 s.s. and is also available in 1½ inch flat plate (yield of 110,000 psi). The 316 s.s. costs approximately \$3.50/lb while the Ti 6Al 4Vn is about \$40/lb. The titanium alloy has a modulus of about 50% that of steel, which would perhaps be of theoretical benefit in off-setting the greater size of the stem to maintain stem flexibility. One possible reservation in the use of this material might be the bearing properties against polyethylene in the presence of acrylic debris. Tests in our laboratory with this alloy have indicated a potential problem in terms of severe scratching of the Ti 6Al 4Vn with massive release of metal debris particles. This phenomenon has not been observed in removed clinical implants. We emphasize that this is a potential clinical problem, but not as yet an actual one. Clinically, we have not observed this scratching. We have implanted thirteen Titanium T-28 femoral components in patients requiring exceptional metal strength or who have a suspected cobalt sensitivity. One of those has been removed and the wear surfaces show no excessive scratching, although acrylic debris was not found in this cup. Our current technique dictates that all acrylic be carefully trimmed from the bone margins so that acrylic dislodgement due to loosening or dislocation would be a remote possibility.

At the time of the initial grant application, 316 s.s. was specified as the material of choice because (1) it was readily available in the form required, (2) it could be welded reliably, (3) the glass-metal headers at the stem tip were available in 316 s.s. from a vendor which JPL had dealt with. We have since verified that our welding subcontractor can weld Titanium alloy and an alternate vendor has been located to produce the three pin headers in Titanium alloy on special order. Therefore, there is no reason why Titanium alloy cannot be used for our implant.

Both materials are acceptable in terms of biocompatibility performance. In terms of mechanical performance, the Titanium alloy has over 2½ times yield strength of 316 s.s. and undoubtedly superior performance in terms of fatigue loading. However, if the stem cross-section is large and the bending stresses low, the 316 s.s. will also have acceptable mechanical performance. The configuration of our first prototype implant is shown in the accompanying drawings. An aluminum model has been machined out of a solid block of material for implant trials in a number of cadaver femurs. The stem cross-section is slightly larger than revision stems in clinical use at UCLA and a patient with a somewhat larger than normal femoral canal will be needed for the clinical implantation. At the proximal section of the stem where the bend begins, the area moment of inertia of the cross-section is 2.5 times greater than the extra-large stem T-28 prosthesis which is fabricated from 316 s.s. At the lower level of the prototype stem near



the tip of the induction coil, the ratio is 1.6. There have been no reported stem failures of the extra-large T-28 prosthesis, nor of the revision prosthesis in clinical use at UCLA and other centers since 1971.

Although we feel that 316 s.s. would be satisfactory for our application in the implant configuration proposed, we can also appreciate the reviewer's suggestion that a stronger material be used to reduce the possibility of mechanical failure of the implant. At the present time, two prototype implants in the configuration shown in the accompanying drawings are being machined in 316 s.s. for preliminary evaluation. The twelve units for mechanical testing will be machined from Titanium alloy. If the mechanical performance is satisfactory, this will be the material of choice for our clinical implant units. One additional advantage of the Titanium alloy is the reduced modulus of elasticity which should give us approximately twice the strain signal for each gauge when compared to 316 s.s. The lower modulus Titanium alloy will help to off-set the increased cross-sectional size of the stem in maintaining stem flexibility. It is also possible that the stem size can be reduced with the higher strength material allowing wider range for patient selection.

Because of the increased cost of the Titanium alloy, we will need to increase our supplies budget by \$5,500 to cover the added expense for implant fabrication.

#### 6. Effect of Stem Size on Stem Stress

Finite element analyses of the well-cemented femoral total hip component have suggested that a stiffer stem will carry a greater portion of the hip load. Although in some instances the stress in the stem may increase slightly for certain configuration, the stem stresses for a well-cemented component are relatively low, as our strain gauge studies and those of others have shown. Fatigue failure of well-cemented and well-supported stems is rare; now failures are associated with loosening and cracked acrylic. One advantage of a stiffer stem (well-cemented) is the fact that acrylic stresses are generally lower. We feel that lower acrylic stresses are desired since the margin of safety of this relatively weak, brittle material is much less than that for the metal component. Cement failure is usually the first weak link in the chain of events leading to stem failure. The stiffer stem may help to prevent this occurrence. If loosening should occur, the larger stem will be more resistant to fatigue in the unsupported (cantilever) fatigue mode of stem fracture.

#### 7. Efficiency of the Power Induction System

The induction system is not a weak link in our project plan. Since the submission of the grant proposal application, several design modifications implemented in the power induction system have resulted in significant improvements to induction power transfer and overall system efficiency. These design improvements include: (1) a flat-wound (single layer) primary induction coil, (2) hi Q resonating and coupling capacitors, (3) a replacement drive transistor more suitable for high current coupling to the induction coil and, (4) decoupling of the secondary coil from the stem with a Delrin dielectric sleeve.

A fully operational 316 s.s. mock prosthesis (shown in the attached photo next to the aluminum prototype model) with these modifications implemented was tested in a fresh cadaver leg to determine induction power transfer efficiency and external coil placement sensitivity. The mock implant stem is shorter than the stem of the prototype design. In order to assure that the

coil would be located in the correct position within the femoral canal, the proximal femur was cut off shorter to permit proper stem tip placement. In the accompanying photo, the mock implant is in place in the bone, and the aluminum prototype is held in the approximate position it would occupy with respect to the normal anatomy. The external coil is shown in the optimum position centered over the pickup coil. The cap of the mock implant has been removed and two leads for induced voltage measurements were connected to a digital voltmeter.

In the optimum coil position shown, a rectified voltage of 19.8 v DC was obtained with an induction coil DC power of only 4.8 watts. This is a tremendous improvement over our prior system which required 30 watts to achieve the minimum 10.3 volts required for system operation. Position sensitivity should not be a problem: 16.0 volts was measured with the coil displaced  $\pm 3.5$  inches from the optimum position shown without additional primary power. Based upon these test results, we have great confidence that the induction system will perform as desired. Two circuits remain to be designed, the oscillator stage and the buffer, which should require less than 2 watts. Therefore, it is estimated that the induction system will consume a total of 6 watts of DC power at 12 volts which is well within our design goal of 10 watts. A portable battery pack system will also be developed for clinical use.

The fully operational prosthesis complete with telemetry and operational power induction and R.F. antenna coils was tested in a 4 liter water bath to test system functions in a simulated implant configuration. FM transmission tests of the 89 MHz received RF signal level showed an additional loss of only 4 dB with respect to a comparable test in free air at a distance of 2 meters. From this data the expected communication system signal to noise ratio was calculated to be 39 dB. With the signal to noise ratio of 39 dB, the error voltage of the communications link is calculated to be only 1.12% RMS. This places the overall error of the reconstructed telemetered force vector at approximately 10%. We hope to reduce this error to about 5% with further system refinements.

## 8. Strain Gauge Configuration

Eight semiconductor strain gauges are mounted on the inner surface of the prosthesis neck exactly one inch down from the center of the ball. Vertical and horizontal pairs of gauges are wired to measure bending moments in these two planes directly. Four additional gauges equally spaced between these bending gauges are averaged to read the force component acting along the neck axis. The signals from these four gauges are telemetered individually and provide redundancy in case of failure of one or more of the bending gauges. Failure of any one of the four axial gauges would still allow calculation of the axial component by averaging the remaining opposed pair. We have given the placement of gauges careful consideration and believe our configuration to be the most accurate and reliable means for measuring the three vector components of the hip force. Preliminary calibration indicated that we could telemeter measurements of applied force to an accuracy of 9%, which is excellent for our clinical application. A complete and thorough load calibration will be performed for each implant manufactured.

## 9. Project Phases

Based upon our preliminary work and three years of development in this project, we do not foresee any insurmountable barriers and in fact we believe the project is "doable". As we made clear in the first paragraph of

our specific aims, the project will proceed in two phases. The first phase (two years in duration) will be directed towards finalization and testing of an implant design, and the collection of test data for presentation to the human subjects protection committee. It is at this point in time that the NIH can judge whether we have a viable project worthy of continuation. We have attempted to anticipate the type of data required for human use approval, and we are confident that we will be able to demonstrate that the implantable units will not leak or break and, therefore, present minimal additional risk to the patient. As stated in our aims, a follow-up proposal will be forthcoming at the two year point, in which we will request funds for clinical implantation studies.

In terms of the present proposal, at the end of the first year, completed tasks will include finalization of the implant design and a complete calibration of the load cell, completion of the electrical tests of the power induction system, and design of the recovery antenna. Tasks to begin in Year 01 and to be completed in Year 02 will be the mechanical testing, hemiticity testing, biocompatibility testing, development of a portable oscilator and battery pack, fabrication of a de-multiplexer and development of the data recovery and display system.

#### 10. Human Use Approval and the MIT Experience

Human use approval for this project is not guaranteed at the present stage of development. At the end of our two year project period, we believe that approval will be granted. We plan to submit our research plans to the committee very early on in our test program, and to feed them data as it is accumulated. We will work closely with the committee and respond to any suggestion or requirements that they might present during the course of the test program. In this manner, we will answer any questions raised before completion of our tests to avoid any last minute delays that could set back the clinical implantation phase.

We are painfully aware of failure of the MIT group to achieve surgical implantation of their prosthesis. We realize that their project has been funded for many years with low yield. We might anticipate the criticism that if MIT could not do it, why do UCLA and JPL believe they can? We respond to this question in the following way. First, the MIT implant was a hemi-arthroplasty and ours is a total hip. The MIT prosthesis was designed to measure interface pressures at the articular cartilage surface. In order to do this, the wall thickness of the ball was drastically reduced at the locations of the pressure transducers. We have heard that outgassing at the sites of these thin diaphragms was a problem. Another problem with their design was the seal at the stem tip, which was mechanical in nature with a series of snap-rings. Our distal seal will be welded and utilize a type of thermal compression bonded glass-metal feedthrough which is common for aerospace applications where hermetic seals are required. Another reason for delay of their project was the necessity to wait for a suitable patient with exactly the right acetabular size to accept their implant. Since our implant is a total hip, the available patient population is greatly expanded. The UCLA-JPL power induction system is much more efficient, and the telemetry package more compact with far less power requirements. JPL is an acknowledged leader in micro-circuit design and fabrication. Years of experience in producing space-flight hardware will assure proper functioning of the implantable units. UCLA is a total hip replacement center for the metropolitan Los Angeles area. Many contributions to the field have come from the UCLA Biomechanics Research Section. UCLA and JPL are 35 minutes apart by auto. We have established an excellent working relationship together. We are confident the project can and will be

completed as outlined.

### 11. Value of the Retrieved Data

This data will be the first in-vivo loading information from a total hip replacement. Even if only one patient implantation were to be achieved, the information will be invaluable. Direct measurement of hip force with walking aids, casts and modified gait patterns will give relative measures of the effectiveness of these changes. Validation of mathematical models of the hip using force plate inputs will also be a real possibility for each individual patient. We believe the retrieved data will have general use, even though a relatively small sample size is planned.

### 12. Budget for UCLA Portion of the Project

Tasks to be performed at UCLA include:

- a. Implant design modifications, trial implantations, development of surgical instruments for implantation, coil tip design improvements.
- b. Biocompatibility testing - animal management, specimen insertion and retrieval from dogs, histological analysis.
- c. Mechanical Test Program -
  1. Design of mechanical test fixtures.
  2. Complete strain gauging of the stems of two units to be tested in air, analysis of strain gauge data.
  3. Fatigue tests of five sealed units in saline with full monitoring of gauge outputs during testing.
  4. Secondary seal tests of two units in saline with periodic sampling of leached out solutes.
- d. Development of the Data Analysis and Display System. JPL is scheduled to provide a de-multiplexer and FM recording with oscilloscope display of discrete gauge outputs. UCLA has the task of synthesizing the signals in numerous combinations (including alternate redundant modes should gauge failures occur) to allow convenient video display. Extensive software development will be required to project graphical displays of force vectors with slow-motion video overlays of patient activities. Additional development of special statistical analysis routines will be needed for interpretation of the tremendous volume of data to be recorded.

We feel that the budget requested is modest for the UCLA tasks involved.

Strain gauging and analysis of gauge outputs are time consuming tasks. Fatigue testing demands constant attention and periodic monitoring as problems are normally encountered as our past experience has shown. Each implant will undergo a full calibration at UCLA before fatigue cycling, and after test completion as well. Two engineers at 50% time (K.L. Markolf and A.H. Hodgson)

will oversee these tests.

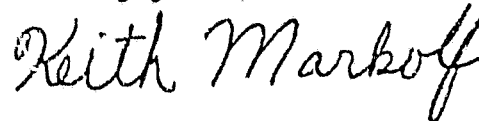
Machining of the implants is a painfully slow process since great precision is required, the material is tough to work, and a large volume of metal is machined away from the "hogging out" process. Prototype fabrication has proceeded at only half the rate we had initially anticipated. In addition to twelve prototype implants, we will need to design and fabricate fatigue test fixtures. A machinist at 50% time has been budgeted. This is an extremely conservative estimate for the tasks required.

The data reduction and computer display are an integral part of this project and will involve extensive software development as outlined. The reviewer misunderstood our intent here: UCLA will not merely apply data acquisition and print-out systems developed by JPL. UCLA will take the raw data (as provided by the JPL receiving console) and synthesize it to a useful form for convenient clinical interpretation. A 50% effort of Dr. Larry Mai will be needed for this task. Again, this is a modest request for a formidable test.

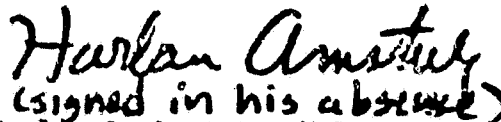
The remaining personnel are necessary for fiscal and administrative management, and preparation of materials for publication and reports. The animal histology will be covered in the dog costs.

We appreciate the opportunity to respond to the reviewer's comments. We hope that the information provided will answer the questions raised. If there is any additional information you or the study section members should require, we would be most pleased to provide it for you.

Sincerely yours,



Keith L. Markolf, Ph.D.  
Adjunct Associate Professor

  
(signed in his absence)

Harlan C. Amstutz, M.D.  
Professor and Chief  
Division of Orthopaedic Surgery

KLM:HCA:cd

Enclosures: Copy of original letter dated 7/15/80, 7 drawings, 2 photographs



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH  
BETHESDA, MARYLAND 20205

July 15, 1980  
Re: AM 27836-01

Dr. Keith L. Markolf  
Adjunct Associate Professor  
of Orthopedics & Biomechanics  
Department of Surgery  
University of California  
405 Hilgard Avenue  
Los Angeles, CA 90024

Dear Dr. Markolf:

When the Applied Physiology & Orthopedics Study Section met in June, they deferred action on your application, AM 27836-01, until additional information could be obtained. I am writing now to request this information.

The first problem area that reviewers met was the lack of specifics about the design of the implantable telemetering device. They felt that the entire system was very sophisticated, but were concerned about certain design aspects. Let me quote from various reviews.

"The technique carries with it some practical problems as well as some theoretical ones. The choice of location point for the pick up coil is a very important one. If the coil is wrapped around the implant stem then there may be considerable alteration in the stress distribution between the stem and the bone when the structure is imbedded in methyl-methacrylate. This alteration would have unknown consequences and would be an additional risk to the patient. In addition, any bulk added to the distal tip of the stem would make removal of the implant extremely difficult in case of infection or other implant/explant situations. While the effect on soft tissue of a radiation field is probably minimal and, indeed, because of the time duration of the radiation the effect on bone is probably minimal, there is still some very small but finite risk associated with that type of radiation. However, that risk probably would not be sufficient to influence the use of this type of technology to power the telemetry device. The most substantial risk in the proposed prosthesis is the design of the stem. The investigators are proposing to use 316 stainless steel as the material and to have holes within

(Continued)

the structure to allow the passage of both the antenna wire which will emerge from the tip of the prosthesis and the power coil which must also be attached to the tip of the prosthesis. At the current time stainless steel devices are not among the safest design and material choices for the orthopedic surgeon. Difficulty with several of these devices is well-known and has been documented in the literature. Both the design of the stem, in that it contains internal cavities, and the choice of 316 as a structural material are probably independent and it is therefore possible to change the material choice without grossly altering the design considerations. It is interesting to note that the Zimmer Corp. has withdrawn from sale their most popular stainless steel stem, the one that is specifically referred to in this proposal, the "T28." This stem was known to undergo fatigue fractures without any associated loosening of the cement. Stainless steel, as a material, is more prone to fatigue damage than some of the other available implant materials and would actually represent a regression in the state-of-the-art should it be used as the material of choice for this prosthesis."

"The concept of making the stem larger in cross-section diameter so as to afford greater strength has its counterpart in the orthopedic literature. A larger stem produces stiffer structures and stiffer structures will share a greater portion of the load in the composite system. Therefore, based on analyses which have appeared in the literature increasing the cross-sectional size of the stem may not necessarily decrease the stress to that stem. Indeed, there are certain configurations where the stresses will actually increase. The main problem is the lack of specific design information and design configuration for the proposed implant."

"The induction system is a weak link in the system and appears to need the most development. If the efficiency of this component cannot be substantially improved it could prejudice the entire project. Consequently, improvement of the induction system should be the first priority of the project. If satisfactory induction of power is not possible, the rest of the development is useless."

"An analysis of signal reception, in a realistic environment which more closely resembles the intended use condition, would be useful. It should be determined that overall accuracy from the system will provide sufficiently accurate strain data under such conditions. It should also be determined that the present strain gauge configuration will provide the optimal data output to answer the desired questions. It would be a shame to construct such a complicated device and fall short of optimal data collection."

(Continued)

Dr. Markolf  
July 15, 1980  
Page 3

"Due to the expense of the project, definite milestones (phases) and decision points should be placed, so that the project could be terminated if an insurmountable barrier is reached or if there is any doubt as to the eventual human application. Such a phased approach could prevent production of an extremely expensive laboratory curiosity."

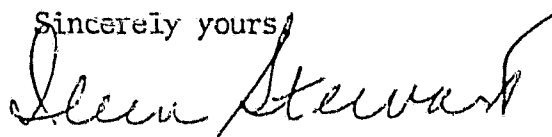
"On the negative side, there is no assurance that an approval for implantation could be obtained from a Human Investigation Committee. Although the design modifications that relate to the size of the ball or size of the prosthetic stem do not represent significant changes in terms of the current state-of-the-art, there are procedures that could increase the risk of failure in a permanent implant. These include the machining required to place electronic components, and the need to decrease some initial dimensions, the presence of seals and other necessary modifications. A program at M.I.T., similar in principle, has been underway for many years and has not yet reached the state of clinical implantation."

"The eventual implantations will be by force, limited to a very small number of subjects, and there will be considerable variability from patient to patient detracting, to some extent, from the value of the information."

"An important point is the cost of this program. A great deal of work is to be done at the Jet Propulsion Laboratories. According to the proposal, the specific tasks that will be accomplished at UCLA are quite limited. They include the manufacturing of 12 prototype prostheses, structural tests in two units in air and in five units in saline, and secondary seal tests in dogs. A total of six animals is planned with multiple implants in each. UCLA will also apply data acquisition and print-out systems developed by JPL. Does this amount of work require two and one-half full-time equivalent persons and the large budget reported for UCLA?"

If you could respond to the above comments in whatever detail is required, we would be most appreciative. I will need your reply by mid-August at the latest. Thank you.

Sincerely yours,



Ileen E. Stewart  
Executive Secretary  
Applied Physiology & Orthopedics  
Study Section  
Division of Research Grants